MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

GENERAL INFORMATION
MEDICAL DEVICES and IVDs

This guideline is intended to provide recommendations to interested persons wishing to submit applications for the licensing of manufacturers, distributors and wholesalers, and registration of medical devices and IVDs. It represents the Council's current thinking on the safety, quality and performance of medical devices and IVDs. It is not intended as an exclusive approach. The council reserves the right to request any additional information to establish the safety, quality and performance of a medical device or IVD in keeping with the knowledge current at the time of evaluation. Alternative approaches may be used but these should be scientifically and technically justified. The Council is committed to ensure that all registered medical devices and IVDs will be of the required quality, safety and performance. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Guidelines and application forms are available from the office of the Registrar and the website.

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DR JC GOUWS

REGISTRAR OF MEDICINES

TABLE OF CONTENTS

Page

1 INTRODUCTION 6

2 GENERAL 7

2.1 Scope 7

2.2 Medical Device Standards and Conformity Assessment Standards 7

2.3 How Medical Devices and IVDsare Regulated in South Africa 7

2.4 Key Elements forthe Regulatory Control of Medical Devices and IVDs 8

2.4.1 Confidentiality/Secrecy 9

2.4.2 Language 10

2.4.3 Where to Submit Applications 10

2.5 Life-Cycle Approach to the Regulation of a Medical Device 10

2.6 Who is the Manufacturer of a Medical Device or IVD 11

2.7 WHO iS THE DISTRIBUTOR OF A MEDICAL DEVICE OR IVD 11

2.8 Responsibilities of a Medical Device Manufacturer and A DISTRIBUTOR 12

2.9 Who needs a licence 12

2.10 Responsibilities of a medical device or IVD licence holder 13

2.11 Processes to Supply Medical Devices or IVDs in South Africa 14

2.12 Summary of Pathways to Licence a Manufacturer to Manufacture, Import, Export and Supply a Medical Device or IVD in South Africa 15

2.13 Summary of Pathways to Licence a DISTRIBUTOR to Import, DISTRIBUTE and Export and Supply a Medical Device or IVD in South Africa 16

2.14 Processes to register a medical device or IVD in South Africa 17

2.15 Process to register all Class B, Class C and Class D Medical Devices or IVDs In South Africa 18

3 CLASSIFICATION OF MEDICAL DEVICES (Non-IVDs) 19

3.1 Overview 19

3.2 Principles for applying the Classification Rules 20

3.3 Medical Devices with a Measuring Function 20

3.4 Examples of Medical Devices and whether they have a Measuring Function 21

3.5 Medical Devices required to be sterile 22

3.6 What Classification Rules apply? 24

3.7 Duration of Use Classification: Transient, Short-Term, and Long-Term Use 26

3.8 Classification of Non-Invasive Medical Devices 26

TABLE OF CONTENTS

Page

3.8.1 Non-invasive medical devices 27
3.8.2 Invasive Medical Devices 29
3.8.3 Active medical devices 35
3.8.4 Additional Classification Rules 13, 14, 15 & 16 39
3.8.5 Classification examples 41

4 CLASSIFICATION OF IVD MEDICAL DEVICES 44
4.1 Overview 44
4.2 Principles for applying the Classification Rules 45
4.3 Classification RULES FOR IVDs 46
4.3.1 Classification Rule 1 - Detection of transmissible agents posing a high public health risk 46
4.3.2 Classification Rule 2 - Detection of red blood cell antigens and antibodies and non red cell typing 47
4.3.3 Classification Rule 3 - Detection of transmissible agents or biological characteristics posing a moderate public health risk or a high personal risk 48
4.3.4 Classification Rule 4 - IVD medical devices for self-testing 51
4.3.5 Classification Rule 5 - Non assay-specific quality control material 52
4.3.6 Classification Rule 6 - Reagents, instruments etc. 52
4.3.7 Classification Rule 7 - Other IVDs are Class B IVD medical devices 55
4.3.8 IVD Classification Flow Chart 56

5 FEES FOR MEDICAL DEVICES and IVDs 57
5.1 Overview 57
5.2 Annual Fees 57
5.3 Fees 58
5.3.1 Application fees 58

6 INCLUDING MEDICAL DEVICES IN THE SA MEDICAL DEVICE OR IVD REGISTER 59
6.1 Overview 59
6.2 Process for including Class A devices in the Medical Device Register or IVD Register 59
6.3 Process for including medical devices other than Class A in the Medical Device Register or IVD Register 60
6.4 Applications for inclusion in the Medical Device Register or IVD Register 61
6.5 Application Audit 61
6.5 TYPES of medical devices 62
6.6 Unique Device Identifiers (UDIs) 62
6.7 Global Medical Device Nomenclature (GMDN) Codes 63

TABLE OF CONTENTS

Page

6.7.1 Device nomenclature system codes 63
6.8 Variants for Class D Devices (including ActiveMedical Devices) 64
7 INFORMATION ABOUT A MEDICAL DEVICE 65
7.1 Overview 65
7.2 Implanted Devices 66
7.3 Instructions for Use 67
7.4 Advertising 68
8 ACTIVE MEDICAL DEVICES 68
8.1 Overview 68
8.2 Different forms of Energy 70
8.3 Electromedical safety standards 72
8.3.1 Medical devices that connect to the public mains electricity supply 72
8.3.2 Electromagnetic Compatibility (EMC) 73
8.3.3 Telecommunications and Radio-Communications Transmitters 74
8.3.4 Radioactive medical devices 74
8.3.5 Radiating medical devices 74
8.3.6 Software 75
9 MEDICAL DEVICES INCORPORATING A MEDICINE 76
9.1 Overview 76
10 MEDICAL DEVICES CONTAINING MATERIALS OF ANIMAL, MICROBIAL OR RECOMBINANT ORIGIN 78
10.1 Overview 78
10.2 Descriptions of the kinds of materials 78
10.3 Medical devices included in Classification Rule 14 80
10.4 Medical devices containing materials of animal origin not classified under Classification Rule 14 80
10.5 Self assessment for animal components where the device is not classified under Classification Rule 14 and conformity assessment by COUNCIL is not required 81
10.6 Conformity assessment procedures for medical devices that contain materials of animal, microbial or recombinant origin 81
10.7 Specific requirements for animal-origin components 83
10.8 Specific requirements for microbial origin components 84
10.9 Specific requirements for recombinant origin components 84
10.10 Options for conformity assessment certification for medical devices containing animal origin

TABLE OF CONTENTS

Page

material....84

11 GROUP, SYSTEMS AND PROCEDURE PACKS....85

11.1 Overview....85

11.2 Regulatory and legislative requirements....85

11.3 Different Types of Packages....86

11.3.1 Systems....86

11.3.2 Procedure packs or procedure kits....87

11.4 Products and articles that are not medical devices....87

11.5 Composite packs....87

11.6 Custom-mademedical devices....88

11.7 Classification of Groups, systems and procedure packs....88

11.8 Conformity assessment procedure options....88

11.8.1 Special Conformity Assessment Procedure....89

11.8.2 Eligibility for the Special Conformity Assessment Procedure....89

11.8.3 Choosing to use the special procedure....90

11.9 Specific types of Groups, systems and procedure packs....93

11.10 Changes to contents....94

11.11 Accessories....94

12 DESTRUCTION OF MEDICAL DEVICES OR IVDS....94

13 NON-RECALL ACTIONS FOR MEDICAL DEVICES....95

14 CANCELLATION OF A MEDICAL DEVICES AND REMOVING FROM THE SA MEDICAL DEVICE REGISTER AND IVD REGISTER....95

UPDATE HISTORY....96

GUIDELINES FOR THE REGISTRATION OF MEDICAL DEVICES AND IVDs

GENERAL INFORMATION

NOTE: These guidelines outline the format and data requirements for preparation and submission of an application for registration of Medical Devices and IVDs, and should be read in conjunction with the Medicines and Related Substances Act, 1965 (Act 101 of 1965), and the Regulations to this Act.

1 INTRODUCTION

The registration of medical devices and IVDs in South Africa is governed by the provisions and requirements of the Medicines and Related Substances Control Act No. 101 of 1965, (hereafter 'the Act') and the Regulations and Guidelines published in terms thereof.

Copies of the legislation can be obtained from the Department of Health website <http://www.doh.gov.za> or the MCC website www.mccza.com

This guideline provides a consolidated reference document detailing the regulatory requirements for medical devices and IVDs in South Africa and describes the information to be supplied with applications to import, export, manufacture and supply medical devices and IVDs in South Africa. The guidelines also describe post-marketing requirements for medical devices and IVDs.

The information submitted will be evaluated in terms of the provisions of the Act.

The aim of these Guidelines is to assist applicants in the preparation of documentation for the licensing of manufacturers, distributors and wholesalers and registration of medical devices or IVDs. The types of medical devices or IVDs include all products classified as per the different Classes based on a risk assessment and intended use.

It is a legal requirement that data submitted for evaluation should substantiate all claims and should meet technical requirements of **quality**, **safety** and **performance** of the product for the purposes for which it is intended. The Guidelines are meant to guide the applicant in meeting the requirements of the Act. It is acknowledged, however, that in some instances scientific developments may dictate alternative approaches. When a deviation from a guideline is decided on, a detailed motivation giving the reason(s) for the deviation and justification for the alternative approach should be included in the expert report submitted with the application.

Whenever there is doubt, applicants are advised to consult the Council (MCC) for confirmation and/or clarification before completing and submitting the application form; refer to the website for contact details. Applicants should always refer to the **current** version of the relevant ***Guidelines for the Registration of Medical Devices and IVDs*** and the Addenda thereto before completing the application form.

Guidelines are constantly evolving as a result of scientific developments and harmonisation of the requirements of regional and international regulatory authorities. The Council (MCC) endeavours to regularly update the guidelines to reflect current thinking and keep its technical requirements and evaluation policies in line with “best international medical device and IVD regulatory practice”.

2 GENERAL

2.1 SCOPE

A medical device and IVD is defined as per the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended. Legislation requires that the Council shall register all medical devices, except Class A medical devices and custom made devices, and all IVDs, except Class A and B IVDs in terms of such call up notice that the Council has published before it may be sold/marketed.

An application for the registration of a medical device or IVD should therefore be submitted for review and approval. A successful application will result in the inclusion of the medical device or IVD onto the register. These guidelines are relevant only to medical devices and IVDs. Separate guidelines apply to the registration of human medicines including biological and complementary medicines.

2.2 MEDICAL DEVICE STANDARDS AND CONFORMITY ASSESSMENT STANDARDS

Compliance with local and international Medical Device and IVD Standards and Conformity Assessment Standards can be used to demonstrate compliance with the medical device and IVD legislative requirements. The use of these standards is not mandatory, but is one way to establish compliance with the regulatory requirements. The standards cover topics such as: clinical evidence, risk management, medical devices required to be sterile, quality management systems and quality assurance techniques and sterility

The legislative framework adopts the philosophies of the International Medical Device Regulators Forum (IMDRF) (previously known as the Global Harmonization Task Force (GHTF)), an international forum that was established to achieve greater uniformity between national medical device regulatory systems.

2.3 HOW MEDICAL DEVICES AND IVDSARE REGULATED IN SOUTH AFRICA

The Medicines Control Council (Council) is a statutory body that is appointed by the Minister of Health. Its main purpose is to safeguard and protect the public through ensuring that all products (including medicines and scheduled substances) and, medical devices and *in vitro* diagnostics (IVDs) that are sold and used in South Africa are safe, therapeutically effective and consistently meet acceptable standards of quality.

Applications for clinical investigations and evaluations and for registration of medicines and medical devices are reviewed by Council expert committee(s), which considers amongst other issues the scientific, medical and ethical issues of the applications. Proof of safety, quality and performance must be submitted when applying to the Council for approval and registration of a medical device and IVD for use in South Africa. The Council is also responsible for post-market regulation and vigilance.

Regulatory systems are intended to ensure a high level of protection of public health and safety. Public trust and confidence in medical devices and IVDs and in the administrative systems by which they are regulated are based on the safety and performance of devices throughout their life cycle.

In order for the Council to maintain public confidence in the safety, performance, benefits and risks associated with the use of medical devices& IVDs on the South African market, assessments may be conducted:

- before a device is able to be supplied to the market in South Africa, and
- while a medical device is available on the market.

2.3 How Medical Devices and IVDs are regulated in South Africa - continued

Before a new medical device or IVD can be supplied to the market in South Africa, the Council needs to be involved. The regulatory requirements vary, depending on what the device is, the nature of the change (if any) and how it is to be used.

The risks associated with using medical devices can range from little or low potential risk to patients and users to significant potential risks. The level of assessment performed by the Council before the device is able to be supplied in South Africa directly relates to the level of potential risk.

One of the strategies to reduce the regulatory burden on industry globally is to harmonise the approach and to negotiate agreements with other international regulators. These agreements can range from recognition and acceptance of regulatory decisions on specific products to the sharing of information about regulatory processes, such as what pre-market assessments occur before a product is able to be supplied.

The operating costs of the Council are funded by Government and through fees and charges collected from the pharmaceutical and medical device industry. Applicants are required to pay fees for making and maintaining applications to the Council, and licence holders must pay annual charges for the facilities and devices that they are responsible for.

2.4 KEY ELEMENTS FORTHE REGULATORY CONTROL OF MEDICAL DEVICES AND IVDs

The key elements of the regulatory control of medical device and IVDs include:

- requirements for a person or entity to hold a licence to manufacture, import, export, wholesale and or distribute a medical device and or IVD in South Africa. The register of licence holders is a record of all the authorised persons and entities who are legally responsible for the medical devices and IVDs on the market.
- product requirements (the Essential Principles) for the quality, safety, and performance of the medical device that must be complied with:
  - before the device is supplied to the market in South Africa, and
  - on an ongoing basis while the device is supplied to the market in South Africa
- a device classification scheme based on different levels of risk
- options as to how compliance with the Essential Principles can be demonstrated
- the optional use of recognised standards
- ongoing monitoring of medical devices & IVDs that are available on the market
- regulatory controls for the manufacturing processes of medical devices& IVDs
- the Medical Device and IVD Register as a central point of control for the legal supply of medical devices and IVDs in South Africa
- the provision for imposing penalties where regulatory requirements are breached
- a range of corrective actions that may be taken if there is a problem with a medical device or IVD

The legislation also makes provision for specific types of medical devices, including:

- single-use devices
- active medical devices (energy using)
- medical devices that contain a pharmaceutical ingredient
- systems or procedure packs
- custom-made medical devices

2.4 Key Elements for the Regulatory Control of Medical Devices and IVDs - continued

The majority of medical devices and IVDs must be included in the respective register before being made available for supply in South Africa.

Applications for inclusion of a medical device or IVD in the register are submitted through the office of the Registrar of Medicines for consideration by the Medicines Control Council. For a medical device or IVD to be included in the register, the Council must be satisfied that evidence exists appropriate to the perceived risks of the medical device or IVD to support its safe and effective use, and that an appropriate system is in place for monitoring the ongoing performance and safety of the device. If someone intends to supply a device that is identical to a device that is already in the register, even if both devices are made by the same manufacturer, an application to include the device in the register must still be made to the Council.

Furthermore it is necessary to obtain a manufacturer's licence to manufacture, import and or export and or a distributor licence to import, export and distribute and or a wholesaler licence to wholesale and or distribute a medical device and or IVD in South Africa. The register of licence holders is a record of all the authorised persons and entities who are legally responsible for the medical devices and IVDs on the market in South Africa.

The Council may conduct an evaluation of the conformity assessment documentation that demonstrates compliance with the Essential Principles for:

- Manufacturers
- Class D high-risk devices, including devices that contain a pharmaceutical active ingredient:
- a Class C medical device that has not been assessed under a Mutual Recognition Agreement with another regulatory authority or if Council is not aligning itself with another regulatory authority.
- There are medical devices and IVDs that must undergo a mandatory application review audit prior to being included in the register unless the medical device or IVD has been assessed under a Mutual Recognition Agreement with another regulatory authority or if Council aligns itself with another regulatory authority, and supporting evidence is available of the current status with the respective country authority.

2.4.1 Confidentiality/Secrecy

The confidentiality of information submitted to the MCC is governed by Section 34 of the Act. The MCC, committee members or staff of the Medicines Regulatory Affairs (MRA), may NOT

- disclose to any person, any information acquired in the exercise of powers or performance of functions under the Act and relating to the business affairs of any person, except
  - for the purpose of exercising his/her powers, or for the performance of his/her functions under the Act, or
  - when required to do so by any competent court or under any law, or
  - with the written authority of the Director-General, or
- use such information for self-gain or for the benefit of his employer.

The MCC may insist on written confirmation of the identity and affiliation of an individual inquiring telephonically, or in person, about a medicine. No information shall be disclosed telephonically unless the Medicines Control Officer knows the enquirer is entitled to receive the information.

2.4.2 Language

In terms of Regulation 22(4) of the Act, all applications and supporting data submitted to the MCC should be presented in English). Original documents not in English should be accompanied by an English translation.

2.4.3 Where to Submit Applications

Applications should be posted to Private Bag X 828, Pretoria, 0001 or preferably be delivered by the applicant, rather than a courier, to Room NG090, Civitas Building, Thabo Sehume (Andries) Street, Pretoria, where they will be logged and acknowledged. All correspondence should be addressed to the Registrar of Medicines and should be clearly coded as Medical Devices.

The MCC will not take responsibility for documents posted or delivered to any other place or in any other manner.

2.5 LIFE-CYCLE APPROACH TO THE REGULATION OF A MEDICAL DEVICE

Stage	Required regulatory action
Concept	Consider the Essential Principles
Prototype	Incorporate the Essential Principles into the design
Preclinical	Seek approval from or notify the Council of intention to commence clinical investigation and evaluation
Clinical	Follow clinical investigation guidelines Prepare clinical evaluation of clinical data
Manufacturing	Apply conformity assessment procedures and then obtain appropriate conformity assessment evidence
Establishment Licence	Make application for • a manufacturer licence (to manufacture, import or export a medical device or IVD) and or • a distributor licence (to import, export and distribute a medical device or IVD) and or • a wholesaler licence (to wholesale and or distribute a medical device or IVD).
Registration	Use technical documentation, supported by certified assessment evidence, to prepare South African Declaration of Conformity and make application for inclusion of the medical device or IVD into the Register of Medical Devices or Register of IVDs.
Marketing	Adhere to Act 101 of 1965 as amended, and supporting regulations and guidelines
Supply	Monitor safety and performance of the medical device or IVD during its lifetime Maintain conformity assessment evidence Report any problems with the medical device or IVD to the Council and to the users of the medical device or IVD Recall and/or correct medical devices or IVDs that have defects, design flaws, or unacceptable clinical risks or levels of performance
Obsolescence	Notify the Council so the medical device or IVD can be removed from the register.

2.6 WHO IS THE MANUFACTURER OF A MEDICAL DEVICE OR IVD

In terms of the provisions of the Medicines and Related Substances Act, 1965 and in according to the view of the Council, a manufacturer of a medical device and IVD is regarded as

(i) the natural or legal person with the responsibility for the design, manufacture, packaging and labelling of a medical device or IVD before it is placed on the market under the natural or legal person's own name, or in the name of a company, regardless of whether these operations are carried out by that person by himself or on his behalf by a third party; or

(ii) any other person who assembles, packages, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device or IVD with a view to their being placed on the market under the natural or legal person's own name, apart from a person who assembles or adapts medical devices or IVDs already on the market to their intended purpose for patients;

(iii) is responsible for the final release of the Medical Device to the market.

With "manufacture" meaning all operations including the design, purchasing of material, specification development, production, fabrication, assembly, processing, releasing, packaging, repackaging, and labelling of a medical device or IVD as the case may be, including putting a collection of medical devices or IVDs, and possibly other products, together for a medical purpose in accordance with quality assurance and related controls.

A person is not regarded the manufacturer of a medical device if:

- the person assembles or adapts the device for an individual patient; and
- the device is procured from the retail sector ; and
- the assembly or adaptation does not change the intended purpose for the device by means of information supplied by the primary importer on or in any one or more of the following:
  - the labelling on the device;
  - the instructions for using the device;
  - any advertising material relating to the device.
  - technical documentation describing the mechanism of action of the device

In addition, in accordance with the provisions of the Act, a custom made medical device means any medical device specifically made in accordance with a written prescription given by a person authorised for the same by virtue of professional qualifications and in accordance with specific design characteristics and is intended for the sole use of a particular user and excludes mass produced medical devices which only need adaptation to meet the specific requirements of the health professional user.

2.7 WHO IS THE DISTRIBUTOR OF A MEDICAL DEVICE OR IVD

In terms of the provisions of the Medicines and Related Substances Act, 1965 and in according to the view of the Council, a distributor of a medical device and IVD is regarded as

(i) the natural or legal person who imports or exports a medical device or IVD which is on the register for medical devices or on the register for IVDs in its final form, wrapping and packaging, with a view to their being placed on the market under the natural or legal person's own name and sells them to a healthcare professional, healthcare institution, wholesaler or the user;

(ii) is responsible for the final release of the Medical Device to the market.

2.8 RESPONSIBILITIES OF A MEDICAL DEVICE MANUFACTURER AND A DISTRIBUTOR

Manufacturers and Distributors must for each medical device, determine the:

- classification (according to the technical rules provided by Council)
- intended purpose
- appropriate nomenclature system code
- select and apply appropriate conformity assessment procedures to demonstrate compliance with the Essential Principles as prescribed by Council
- ensure that appropriate processes and documentation are in place to before they apply to a Conformity Assessment Body for conformity assessment evidence
- obtain the conformity assessment evidence and certification and ensure the information on the certificate remains current and valid
- pay the application and assessment fees for obtaining the conformity assessment evidence
- prepare a South African Declaration of Conformity which declares compliance to the Essential Principles and specifies the conformity assessment pathway that was used, based on a review of the manufacturing details and tests contained in the technical documentation for the medical device/s and IVDs
- ensure that their conformity assessment procedures are appropriately maintained once they obtain the necessary conformity assessment evidence and certification, and that the ongoing requirements are met (for example, reporting adverse events, regular quality systems audits)
- notify the Council of substantial changes to the design, production, safety or intended performance or risk of the device.

The Council must be notified in writing by the authorised representative, within 1 months of the event occurring, if the manufacturer:

- dies or is no longer operational
- is declared bankrupt
- is a body corporate that is wound up.

Note: Even though submission of conformity assessment evidence is not required for manufacturers of Class A medical devices and IVDs the manufacturer is still required to prepare the necessary technical documentation and a Declaration of Conformity (South Africa) or other Declaration of Conformity (as certified under a Mutual Recognition Agreement with any of the national regulatory authorities that Council aligns itself with), and provide it to the Council upon request.

2.9 WHO NEEDS A LICENCE

To

A) Manufacture, Import, Export Medical Devices or IVDs, or

B) Import, Export or Distribute Medical Devices or IVDs, or

C) Act as a Wholesaler of Medical Devices or IVDs

In accordance with the provisions of Section 22C(1)(b) of the Medicines and Related Substances Act no medical device or IVD manufacturer, distributor or wholesaler shall manufacture, act as a distributor or act as a wholesaler, as the case may be, of any medical device or IVD unless he or she is the holder of a licence contemplated in the said subsection.

2.9 Who needs a licence - continued

In relation to medical devices and IVDs this means:

- a person who, in South Africa, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in South Africa or elsewhere);
- a person who imports, or arranges the importation of, the goods into South Africa and distributes the goods, for supply (whether in South Africa or elsewhere); or
- a person who exports, or arranges the exportation of, the goods from South Africa; or
- a person who acts as a wholesaler of the goods in South Africa

is required to make application to the Council for a licence to

(i) manufacture, import, export, or
(ii) importand distribute and export, or
(iii) act as a wholesaler of medical devices or IVDs and

register the medical device or IVD with the Council

before a person can commence business and supply a medical device or IVD for sale in South Africa..

The licence applicant and licensee must provide, and keep up-to-date the details of

- the owner of the business,
- the designated authorised representative, who is

a natural person who resides in South Africa and who will be responsible to Council for compliance with the laws of South Africa,

- registration of a pharmacist (where applicable),
- qualifications of the staff to manufacture, store, distribute, sell, maintain or repair medical devices or IVDs
- a current certified quality management system, as identified by Council.

The quality management system must include information relating to whom each medical device or IVD has been supplied and in the case of a distributor or wholesaler the details of the entity which supplied the medical device or IVD.

Details of the type of medical device or IVDs (by group or family) which will be manufactured, imported, distributed, exported and sold must be specified by the licence applicant.

Additional information may be requested of the licence applicant by Council.

2.10 RESPONSIBILITIES OF A MEDICAL DEVICE OR IVD LICENCE HOLDER

The holder of a licence to manufacture, import, export, distribute or act as a wholesaler of a medical device or IVD must:

- have procedures in place, including a written agreement with the manufacturer or distributor, to obtain information from the manufacturer or distributor when requested by the Council
- ensure that
  - they have available sufficient information to substantiate compliance with the Essential Principles *(see Guideline 8.02 Essential Principles)*or have procedures in place to ensure that such information can be provided from the manufacturer or distributor to the Council when requested

2.10 Responsibilities of a medical device or IVD licence holder

- an appropriate conformity assessment procedure has been applied to the medical devices or IVDs
- the manufacturer has appropriate conformity assessment evidence for the medical device or IVD
- the conformity assessment certificate remains valid while the device is supplied in South Africa
- for devices other than Class A submit the conformity assessment certificate to the Council with the South African Declaration of Conformity

- complete the Licence application form for a manufacturer licence (see Annexure A) or a distributor licence or a wholesale licence (see Annexure B), pay the licence application and inspection fees to include the establishment in the Register of Licensees
- upon request
  - provide documentation relating to the medical device or IVD to the Council
  - deliver samples of the medical device or IVD to the Council
  - allow an inspector authorised by the Director-General and Council to enter and inspect any premises, including outside South Africa, where the medical devices or IVDs are manufactured or located
- notify the Council of certain incidents and performance issues
- ensure the information about the medical device or IVD complies with the regulatory requirements pay the annual charges for ongoing inclusion in the register of licence holders and for ongoing inclusion of the medical device or IVD in the medical device or IVD register

There arepenalties,including fines or imprisonment, for any person who makes false statements and or contravenes the provisions of the law.

2.11 PROCESSES TO SUPPLY MEDICAL DEVICES OR IVDS IN SOUTH AFRICA

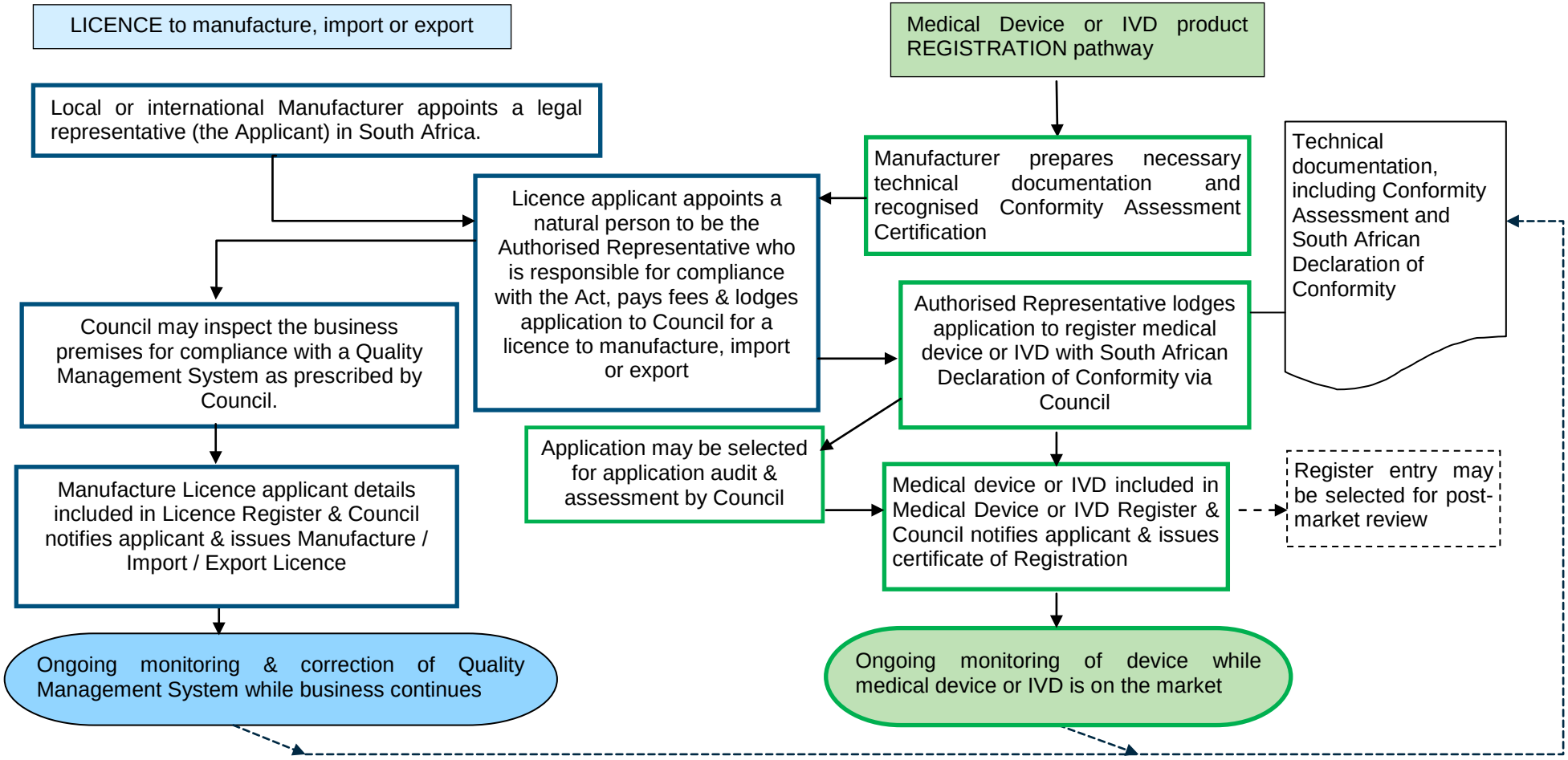
There are different processes that must be followed to be able to supply medical devices and IVDs for sale in South Africa, depending on where the medical device or IVD is manufactured.

The general requirement to commence business and to supply / sell a medical device or IVD, regardless of place of manufacture or classification, includethe two processes i.e.

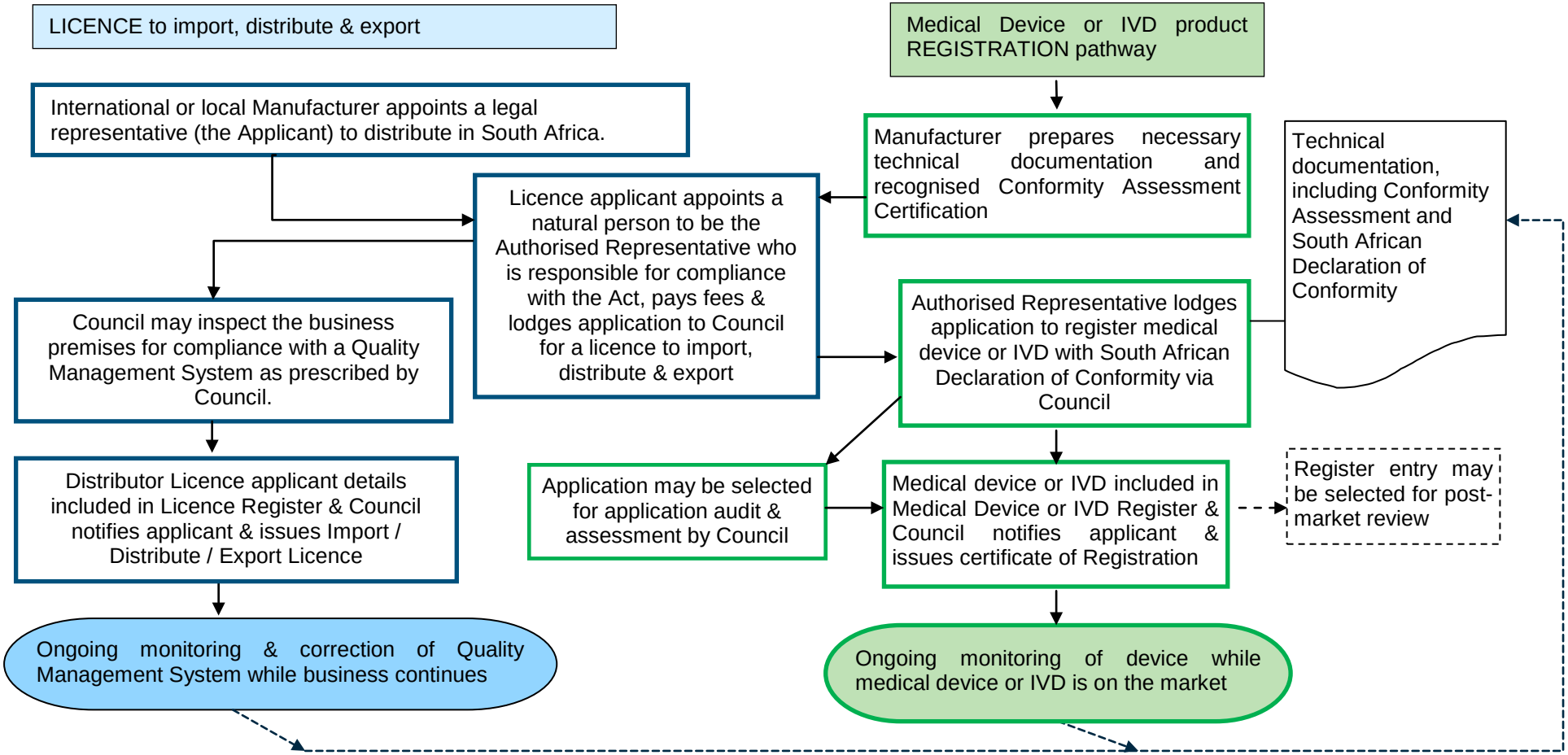
(i) obtain a manufacturer licence to manufacture or import or export medical devices or IVDs,

(ii) register a medical device or IVD

2.12 SUMMARY OF PATHWAYS TO LICENCE A MANUFACTURER TO MANUFACTURE, IMPORT, EXPORT AND SUPPLY A MEDICAL DEVICE OR IVD IN SOUTH AFRICA



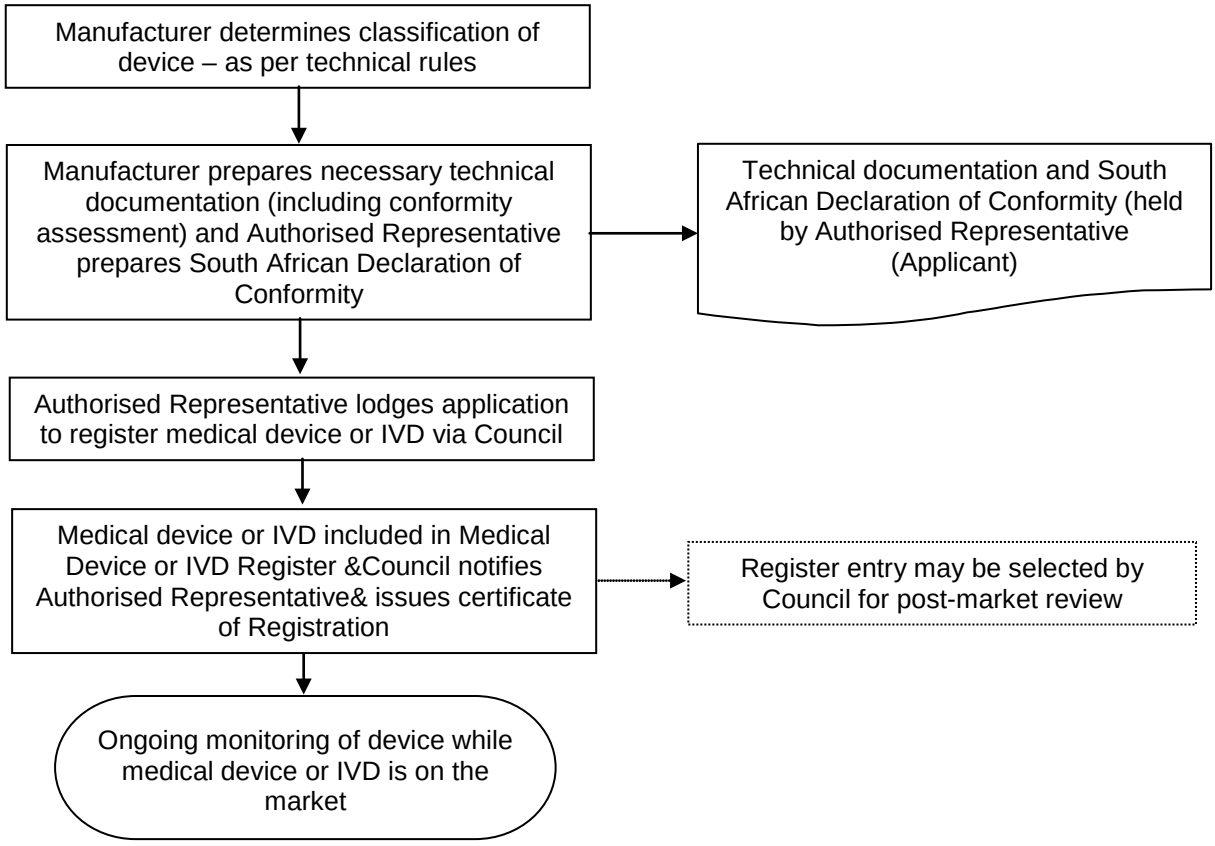
2.13 SUMMARY OF PATHWAYS TO LICENCE A DISTRIBUTOR TO IMPORT, DISTRIBUTE AND EXPORT AND SUPPLY A MEDICAL DEVICE OR IVD IN SOUTH AFRICA



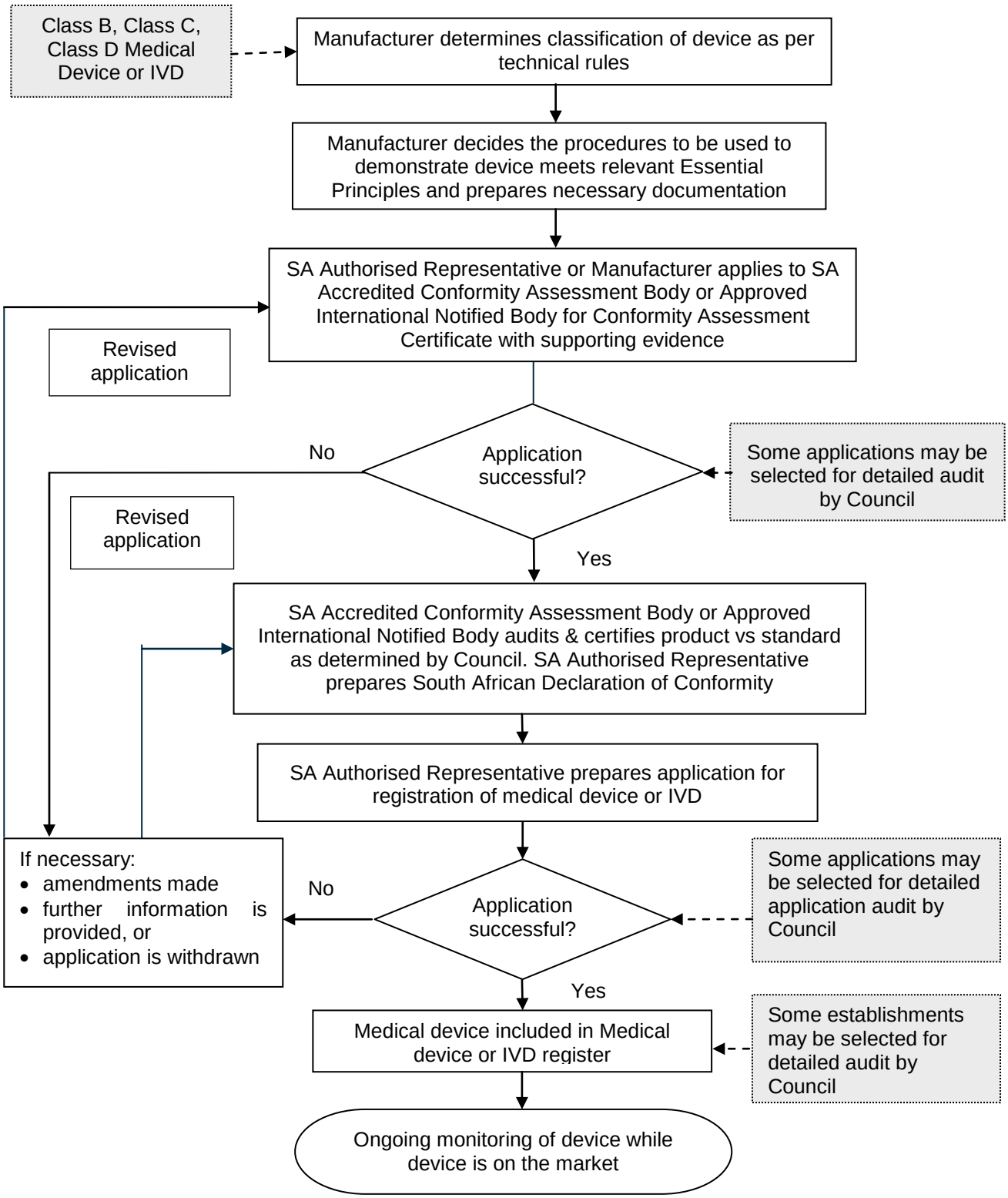
2.14 PROCESSES TO REGISTER A MEDICAL DEVICE OR IVD IN SOUTH AFRICA

The specific processes to acquire registration of a medical device or IVD, depends on the classification of the medical device or IVD. There are two processes:

- Process to supply a Low risk Class A medical device or IVD in South Africa
- Process to supply a Class B, Class C, and Class D medical device or IVD in South Africa.



2.15 PROCESS TO REGISTER ALL CLASS B, CLASS C AND CLASS D MEDICAL DEVICES OR IVDS IN SOUTH AFRICA



3 CLASSIFICATION OF MEDICAL DEVICES (Non-IVDs)

3.1 OVERVIEW

The medical devices regulatory framework has a classification system for medical devices and IVDs, as per Medical Device Regulation 12 of Act 101 of 1965.

A medical device, other than an IVD medical device, has the medical device classification applying under the classification rules set out in the Technical Rules for Classification of Medical Devices.

An IVD medical device has the medical device classification applying under the classification rules set out in the Technical Rules for Classification of IVDs.

The classification levels for medical devices are:

Classification	Level of risk
Class A	Low risk
Class B	Low–moderate risk
Class C	Moderate – high risk
Class D	High risk Where risk relates to the patient or to public health

The manufacturer or distributor is responsible for determining the classification of a medical device using a set of classification rules supplied by the Council, based on the:

- manufacturer's or distributor's intended use of the device or IVD
- level of risk to patients, users and other persons (the probability of occurrence of harm and the severity of that harm)
- degree of invasiveness in the human body
- duration of use and exposure.

Identical medical devices may be classified differently if they are to be used in different parts of the body. This is why the original manufacturer's intended use of the device is so critical to determining the appropriate classification. The intended use can be obtained from the:

- instructions for use
- label
- original manufacturer's advertising materials
- technical documentation

Note: There may be medical devicesor IVDs where the classification in South Africa is different to the classification in other countries. The applicant should take into account the South African requirements when determining the classification of a device that is to be supplied in South Africa.

3.2 PRINCIPLES FOR APPLYING THE CLASSIFICATION RULES

The classification rules are outlined in technical rules for medical devices those applicable to IVDs and are based on the manufacturer's intended purpose, taking into account the design and how the medical device or IVD works. In some cases, classification is inconclusive and more than one rule can apply. If this happens the higher classification applies.

All the classification rules must be considered to determine the classification of the medical device or IVD. Accessories are classified separate to the medical device they are used with.

If the device is to be used in combination with another medical device, the classification rules must be applied separately to each device.

For groups, systems and procedure packs, the classification for the entire group, system or pack is the highest classification of any individual device in the group, system or pack. The presence of a registered medicine in a procedure pack does not affect the classification. For example, if there is a device in the pack that is classified as Class C, then the entire pack is classified as Class C.

Manufacturers should pay particular attention to *Rules 13, 14, 15 & 16—Additional rules*, as these rules may not be applied consistently internationally.

Software:

- that fits the definition of a medical device is also an active medical device since it relies on an energy source for its operation
- that is intended to make a device operate, control a device, or influence the functions of a device generally falls in the same classification as the device
- intended as an accessory to a medical device should be classified separately from the device with which it is used
- is considered an accessory when it is not essential to the operation of the device.

If the intended purpose of the medical device or IVD is not clear, the Council will request further clarification from the manufacturer or Authorised Representative. If the documentation requested is not provided within the required period or is unclear then the Council will assume an intended purpose consistent with the purpose generally accepted in current clinical practice.

If a medical device is intended to be used in more than one part of a patient's body, the medical device is classified on the assumption that it will be used in the part of the body that poses the highest risk. For invasive devices, this may be the central circulatory or central nervous systems.

In the event of a dispute between the manufacturer and the notified body concerned, resulting from application of the classification rules, the Council shall determine the classification.

3.3 MEDICAL DEVICES WITH A MEASURING FUNCTION

A medical device is considered to have a measuring function if the device is intended by the manufacturer to measure quantitatively a physiological or anatomical parameter:

- a quantity or a qualifiable characteristic of energy or of substances delivered to or removed from the human body.

3.3 Medical Devices with a Measuring Function - continued

The measurements given by a medical device must:

- display in South African legal units of measurement or other units of measurement acceptable to the Council, or
- be compared to at least one point of reference indicated in South African legal units of measurement or other units of measurement acceptable to the Council, and
- be accurate to enable the device to achieve its intended purpose.

The device must meet each of the above requirements to fit the definition of measuring function.

Manufacturers of medical devices that have a measuring function must prepare evidence that the device complies with the relevant Essential Principles, particularly Essential Principle 10. For more information please see Guideline 8.02 Essential Principles

For manufacturers of Class A devices that have a measuring function, in addition to preparing a South African Declaration of Conformity, they must supply the Council with conformity assessment evidence to demonstrate that the relevant Essential Principles have been met.

3.4 EXAMPLES OF MEDICAL DEVICES AND WHETHER THEY HAVE A MEASURING FUNCTION

Device	Requirements to fit the definition of measuring function			Result
	Measurement of physiological/ clinical parameters?	Absolute measurement units/reference	Measurement critical to intended purpose	
Clinical thermometer that displays patient temperature in ºC	Yes	Yes	Yes	Measuring function
Forehead patch that indicates temperature via colour change	Yes	No	Yes	Does not have a measuring function
Time-of-day clock (HH:MM)	No	Yes	Yes	Does not have a measuring function
Medicine measuring cup with ml or defined Units marked	Yes	Yes	Yes	Measuring function
Medicine cup with no scale	Yes	No	No	Does not have a measuring function
“Biofeedback” electromyograph (relative scale)	Yes	No	Yes	Does not have a measuring function
Diagnostic electromyograph	Yes	Yes	Yes	Measuring function

3.5 MEDICAL DEVICES REQUIRED TO BE STERILE

Some medical devices are required to be sterile when used to minimise the risk of infection. Such medical devices should be terminally sterilised to a Sterility Assurance Level (SAL) of at least 10-6, unless this is not possible due to device material incompatibility with the proposed sterilisation process.

It is the responsibility of the manufacturer to determine the most appropriate method for achieving the required SAL for a particular device after due consideration of the design and construction of the device. Some common sterilisation methods are:

- moist heat or steam
- dry heat
- ionising radiation
- ethylene oxide
- liquid chemical sterilisation

Devices that are required to be sterile, but cannot be subjected to terminal sterilisation, can be manufactured aseptically, for example by sterile filtration. Devices manufactured in this manner have a lower SAL than those subjected to terminal sterilisation.

Manufacturers of medical devices that are required to be sterile must prepare evidence that the device complies with:

- Essential Principle 8.3 for devices that are supplied sterile
- Essential Principle 8.1 for devices that are able to be reprocessed

For more information please see *Guideline 8.02 Essential Principles.*

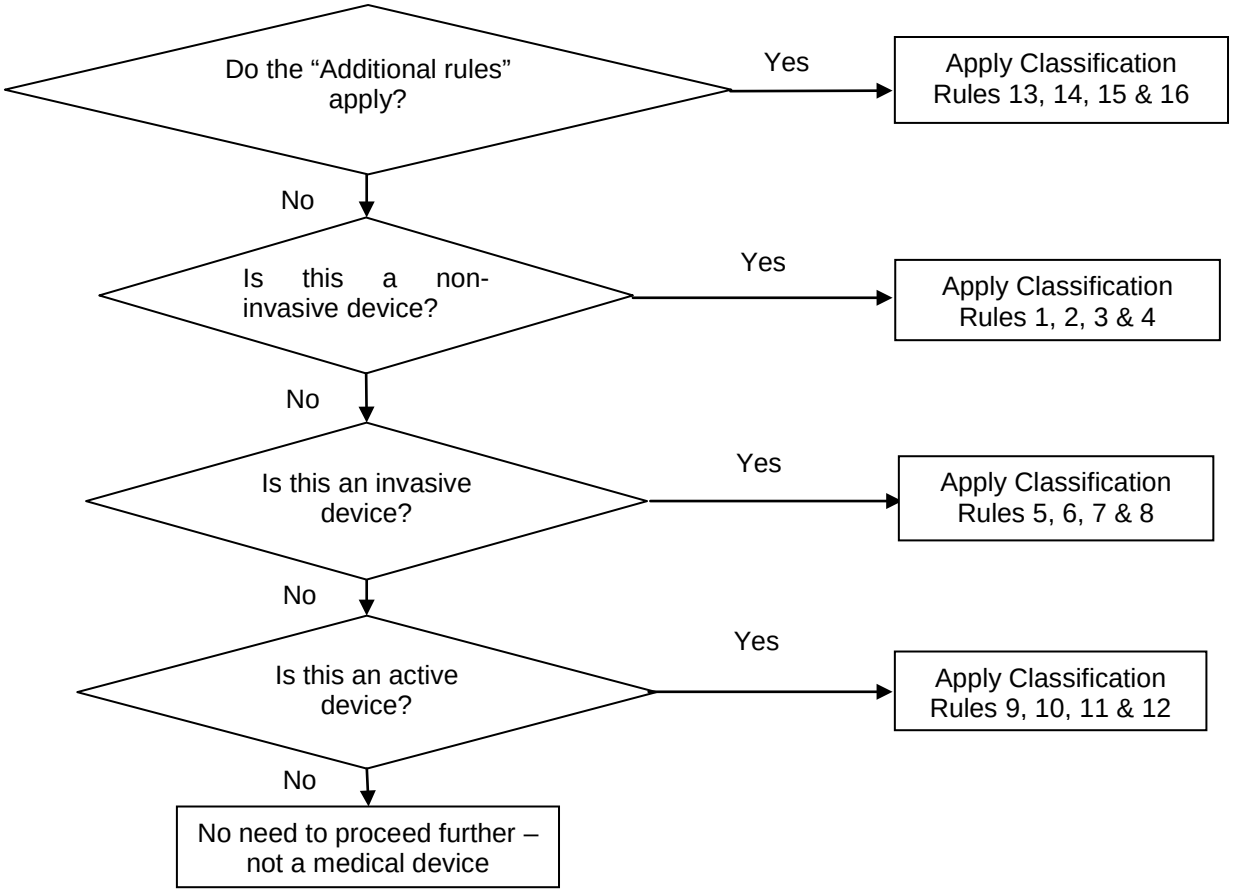
For manufacturers of Class A devices that are required to be sterile, in addition to preparing a South African Declaration of Conformity, they must supply the Council with conformity assessment evidence to demonstrate that the relevant Essential Principles have been met.

Additional standards to consider for sterilisation of Medical Devices are:

Standard	Title
ISO 11135:2014	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11137-1:2006	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-2:2013	Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose
ISO 11137-3:	Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspectsof development, validation and routine control
ISO 17665-1:2006	Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

Standard	Title
ISO 14160: 2011	Sterilization of health care products -- Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives -- Requirements for characterization, development, validation and routine control of a sterilization process for medical devices
ISO 11737-1	Sterilization of medical devices—Microbiological methods—Part 1: Determination of a population of micro-organisms on products
ISO 11737-2:2009	Sterilization of medical devices—Microbiological methods—Part 2: Tests of sterility performed in the validation of a sterilization process
ISO 13408-1:2008	Aseptic processing of health care products—Part 1: General requirements
ISO 13408-2:2003	Aseptic processing of health care products—Part 2: Filtration
ISO 13408-3:2006	Aseptic processing of health care products—Part 3: Lyophilization
ISO 13408-4:2005	Aseptic processing of health care products—Part 4: Clean-in-place technologies
ISO 13408-5:2006	Aseptic processing of health care products—Part 5: Sterilization in place
ISO 13408-6	Aseptic processing of health care products—Part 6: Isolator systems
ISO 14937:2009	Sterilization of health care products—General requirements for characterization of a sterilizing agent and the development of routine control of a sterilization process for medical devices
ISO 17664:2004	Sterilization of medical devices—Information to be provided by the manufacturer for the processing of re sterilisable medical devices

3.6 WHAT CLASSIFICATION RULES APPLY?



Manufacturers should consider all the Classification Rules when determining the appropriate classification for a device as more than one rule may apply and the higher classification applies.

If the device	then apply Classification Rule/s	Some examples are:
is invasive—that is, the device penetrates the body through a body orifice or is inserted into the body during surgery	5, 6, 7 & 8 - classifications vary depending on intended purpose	surgical eye probe, ophthalmic knife, eye cannula, ear/nose/throat forceps, internal tympanostomy tube, tongue depressor, intraoral x-ray sensor, oral gag, oral suction unit, thermometer, vaginal speculum, urethral bougie, anoscope, proctoscope, colonoscope, stomal peg, tracheostomy tube.
is active—that is, the device depends on a source of energy for its operation and converts energy	9, 10, 11 & 12 - classifications vary depending on intended purpose	diagnostic x-ray sources, MRI, air driven surgical drills and saws, patient monitors, electronic blood pressure measuring devices, diagnostic ultrasound, electronic stethoscopes/thermometers, software, gas regulators, radioactive seeds, mechanical infusion systems.
contains a medicine	13 - these devices are Class D	antibiotic bone cements, condoms with spermicide, heparin coated catheters, dressings incorporating an antimicrobial agent.

If the device	then apply Classification Rule/s	Some examples are:
is for contraception or preventing sexually transmitted diseases	16 - classifications vary depending on intended purpose	condoms, contraceptive diaphragms, contraceptive intra-uterine devices (IUDs), surgically implanted contraceptive devices.
is for disinfecting, cleaning, rinsing or hydrating	15- classifications vary depending on intended purpose	contact lens solutions, comfort solutions, disinfectants for haemodialysis devices and endoscopes, sterilisers to sterilise medical devices, washer disinfectors.
not active and is intended to record x-ray diagnostic images	10(i)—these devices are Class B	x-ray films, photostimulable phosphor plates.
Contains viable OR non-viable animal tissues or derivatives	14 - these devices are Class D	biological heart valves, porcine xenograft dressings, catgut sutures, implants and dressings made from collagen, intra-ocular fluids, meniscul joint fluid replacement, anti-adhesion barriers, tissue fillers based on hyaluronic acid derived from bacterial fermentation processes.
is a blood bag	2—these devices are Class C	blood bags (including those containing or coated with an anticoagulant).
is an active implantable medical device	8 - these devices are Class D	implantable pacemakers, defibrillators and nerve stimulators,
is an active device to control, monitor, or directly influence the performance of an active implantable medical device	9(ii) - these devices are Class D	clinician's programming devices for pacemakers, patient control devices for nerve stimulation devices.
is a mammary implant	8 - these devices are Class D	Mammary / breast implants.
is not covered by any of the previous rules in this table	1, 2, 3 & 4 - classifications vary depending on intended purpose	devices intended to: - collect body liquid where a return flow is unlikely - immobilise body parts and/or to apply force or compression - channel or store substances that will eventually be delivered into the body - treat or modify substances that will be delivered into the body - dress wounds.

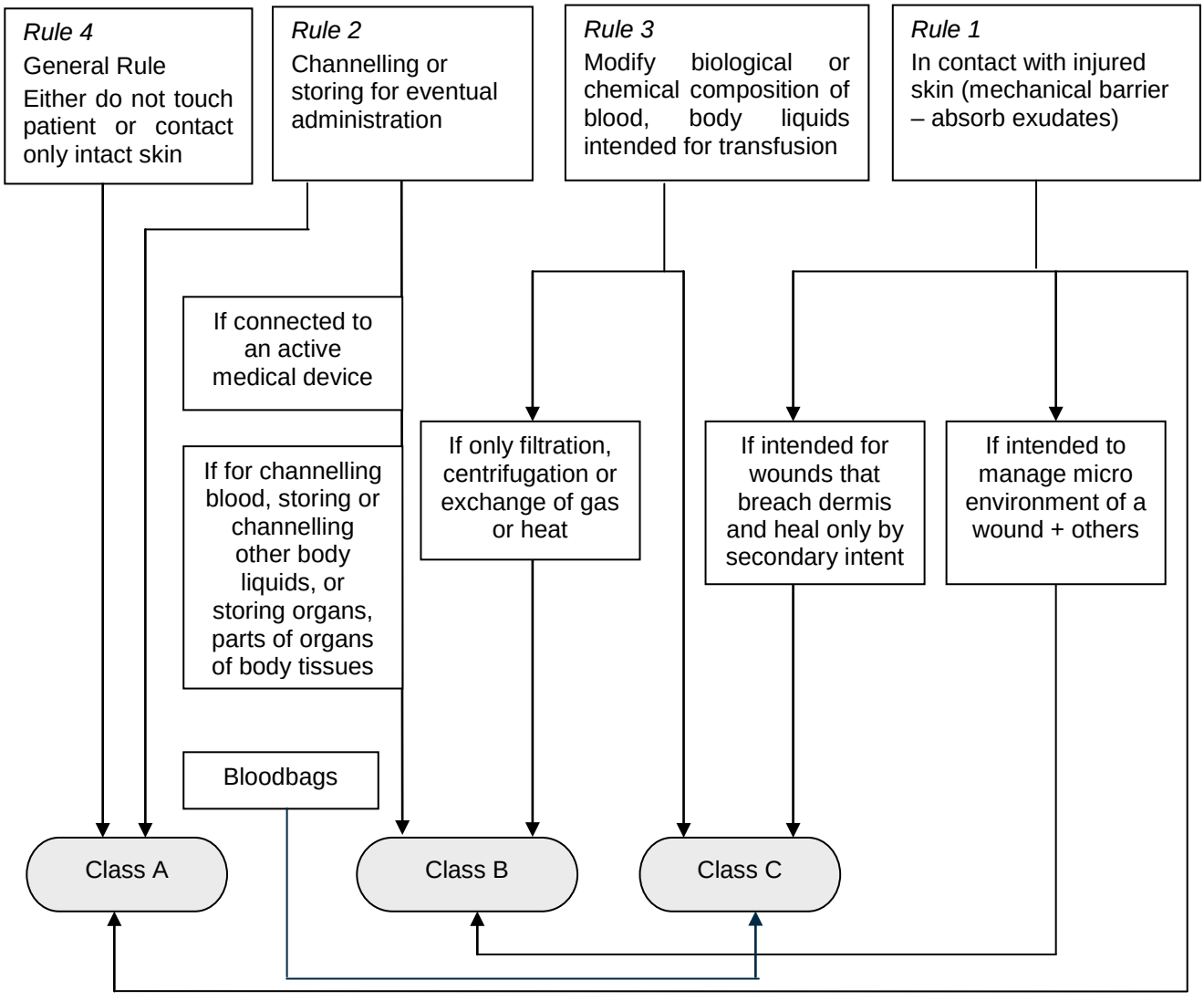
3.7 DURATION OF USE CLASSIFICATION: TRANSIENT, SHORT-TERM, AND LONG-TERM USE

The manufacturer, in determining the classification, must take into account the duration of use:

Period of continuous use	Description
less than 60 minutes	transient
at least 60 minutes but not more than 30 days	short-term
more than 30 days	long-term

3.8 CLASSIFICATION OF NON-INVASIVE MEDICAL DEVICES

This flowchart is a summary of the rules described in the Technical Rules for Classification of Medical Devices.



3.8.1 Non-invasive medical devices

RULE 1: NON-INVASIVE DEVICES INTENDED TO HAVE CONTACT WITH INJURED SKIN

This rule covers wound dressings without consideration of the wound depth. The technology associated with these devices is well understood and they are not considered potentially hazardous to the patient.

Rule 1	Description
1(a) A non-invasive device to be used as a mechanical barrier or for compression or for absorption of exudates—Class A.	Examples: absorbent pads, island dressings, cotton wool, wound strips and gauze dressings to act as a barrier or absorb exudates from the wound. *Note: if the device is sterile conformity evidence is required*.
1(b) A non-invasive device to be used in contact with injured skin (including a device the principal intention of which is to manage the microenvironment of a wound)—Class B.	Assists healing by controlling the level of moisture and regulating the humidity, temperature, levels of oxygen, other gases and pH values of the wound environment, or by influencing the process by other physical means. Examples: adhesives for topical use, polymer film dressings, hydrogel dressings and non-medicated impregnated gauze dressings.
1(c) A non-invasive device to be used for wounds that have breached the dermis and where the wounds can only heal by secondary intent—Class C.	Intended for severe wounds that have extensively breached the dermis, and healing is by secondary intent (by granulation from the base of the wound). Examples: dressings for chronic extensive ulcerated wounds, severe burn, severe decubitus wounds, or dressings providing a temporary skin substitute.

RULE 2: NON-INVASIVE DEVICES INTENDED TO CHANNEL OR STORE BODY LIQUIDS OR TISSUES, LIQUIDS OR GASES

Devices covered under this rule may include those that channel or store substances that will be eventually delivered into the body.

Rule 2	Description
2(a) A non-invasive device used to channel or store body liquids or tissues, liquids or gases that are to be infused, administered or introduced into a patient—Class A.	Intended to be used to channel or store liquids. Examples: administration sets for gravity infusion, syringes without needles.
2(b) A non-invasive device to channel or store a liquid or gas that is to be infused, administered or introduced into a patient and may be connected to an active medical device classified as Class B or higher—Class B.	Examples: oxygen tubing and masks; anaesthetic tubing and breathing circuits; and syringes and tubing for infusion pumps.
2(c) A non-invasive device to channel blood, to store or channel other body liquids, or to store an organ, parts of an organ or body tissue that is to be later introduced into a patient—Class B.	Examples: Tubes for blood transfusion, devices to temporarily store and transport of organs for transplant or for long-term storage of biological substances and tissues such as corneas, sperm and human embryos.

Rule 2	Description
2(d) A non-invasive device to store blood – i.e. blood bags -Class C. *Note: if the blood bags have a function greater than storing purposes and include systems for preservation other than anti-coagulants then other rules may apply.*	Examples: Blood bags which do not incorporate an anticoagulant

RULE 3: NON-INVASIVE DEVICES INTENDED TO MODIFY THE BIOLOGICAL OR CHEMICALCOMPOSITION OF BLOOD, OTHER BODY LIQUIDS OR OTHER LIQUIDS

Devices covered under this rule may include those that modify the biological or chemical composition of substances that will be delivered into the body.

Rule 3	Description
3(a) A non-invasive device to modify the biological or chemical composition of blood, other body liquids, or other liquids to be infused in the patient—Class C.	Devices intended to remove undesirable substances out of the blood by exchange of solutes such as hemodyalizers. Examples: Auto transfusion systems and devices used to separate cells such as gradient medium for sperm.
3(b) A non-invasive device to be used in treatment consisting of filtration, centrifugation or exchanges of gas or heat—Class B.	Examples: particulate filtration of blood in an extracorporeal circulation system, centrifugation of blood for transfusion or autotransfusion, removal of carbon dioxide from the blood and/or adding oxygen, and warming or cooling blood in the extracorporeal circulatory system.

RULE 4: OTHER NON-INVASIVE DEVICES

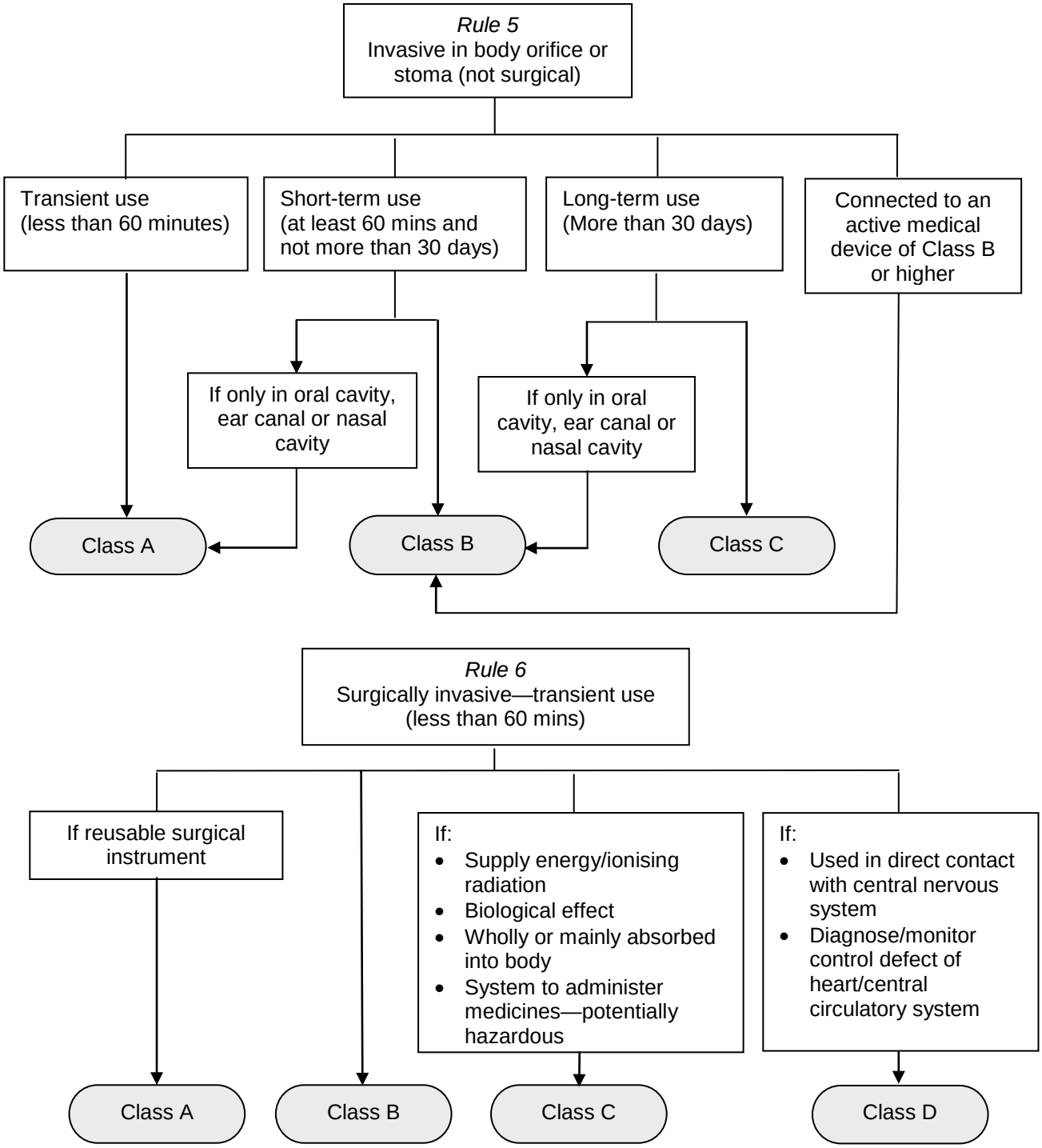
This rule applies to all medical devices that are not covered by a specific rule, devices that contact intact skin and devices that do not touch the patient.

Rule 4	Description
A non-invasive device is Class A, unless the device is classified at a higher level under another rule.	Devices used to collect body liquid where a return flow is unlikely. Examples: urine collection bottles, ostomy pouches, wound drainage collection bottles and incontinence pads. Devices used to immobilise body parts and/or to apply force or compression. Examples: non-sterile dressings, plaster bandages, cervical collars and gravity traction devices or compression hosiery.

3.8.2 Invasive Medical Devices

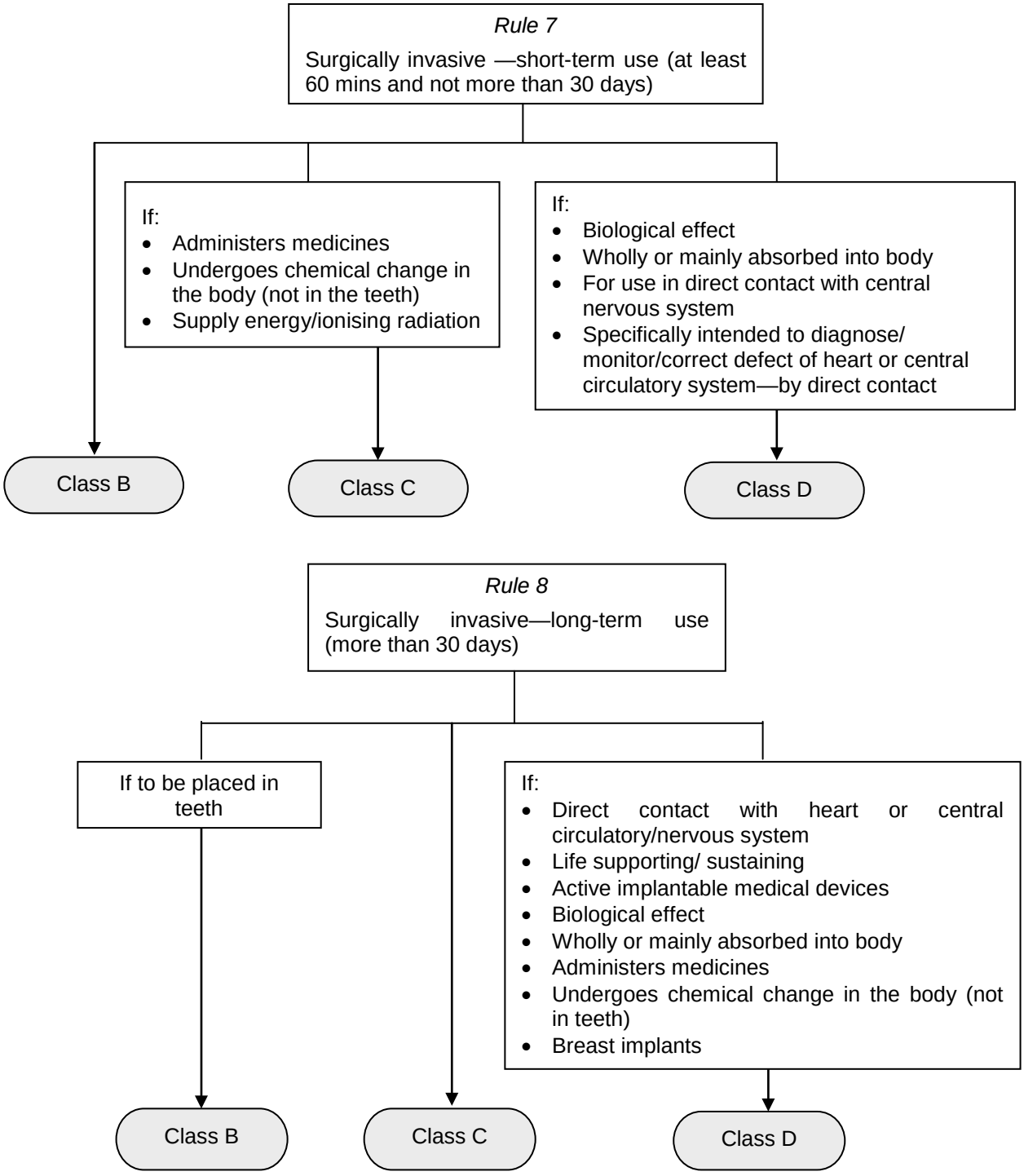
RULES 5 and 6: INVASIVE MEDICAL DEVICES - FLOWCHART

This flowchart is a summary of the classification Rule 5 and Rule 6



RULES 7 AND 8: INVASIVE MEDICAL DEVICES - FLOWCHART

This flowchart is a summary of the rules described in the Technical Rules for Classification of Medical Devices.



RULE 5: INVASIVE DEVICES INTENDED TO BE USED TO PENETRATE BODY ORIFICES

This rule covers devices that enter the body through existing body orifices (for example, ear, mouth, nose, eye) and surgically created stomas. Devices covered by this rule tend to be for diagnostic and therapeutic use in particular specialities (ear, nose, and throat; ophthalmology; dentistry; proctology; urology; and gynaecology).

Rule 5	Description
5(a) Invasive devices that are not connected to an active medical device, or are intended for connection to a Class A medical device only and are for transient use—Class A.	Examples: handheld dental mirrors, dental impression materials, exam gloves, prostatic balloon dilation catheters.
5(b) Invasive devices that are not connected to an active medical device, or are intended for connection to a Class A medical device only and are for short-term use—Class B.	Examples: hard contact lenses, urinary catheters, tracheal tubes, stents, vaginal pessaries, perineal reduction devices.
5(c) Invasive devices that are for short-term use in the oral cavity as far as the pharynx, in an ear canal to the ear drum, or in a nasal cavity—Class A.	Examples: dressing for nose bleeds, dentures removable by the patient.
5(d) Invasive devices that are not connected to an active medical device, or are intended for connection to a Class A medical device only and are for long-term use—Class C.	Examples: long-term urinary catheters, artificial eyes, urethral stents, contact lenses for long-term continuous use.
5(e) Invasive devices for long-term use in the oral cavity as far as the pharynx or in an ear canal to the ear drum, or in a nasal cavity and are not liable to be absorbed by the mucous membrane—Class B.	Examples: orthodontic wire, fixed dental prostheses, fissures sealants.
5(f) Invasive device with respect to body orifices, to be connected to an active medical device that is classified as Class B or higher—Class B.	Examples: tracheostomy tubes connected to a ventilator, powered nasal irrigators, nasopharyngeal airways, heat and moisture exchangers, suction catheters or tubes for stomach drainage. (Independent of the time for which they are invasive)

RULE 6: SURGICALLY INVASIVE DEVICES INTENDED FOR TRANSIENT USE

This rule covers devices that are to be used continuously for less than 60 minutes and are used to create a conduit through the skin (needles, cannulae), surgical instruments (scalpels, saws) and various types of catheters, suckers.

Rule 6	Description
6(a) Surgically invasive device for transient use—Class B.	Examples: suture needles, hypodermic needles and syringes, suckers, surgical swabs, surgical gloves.
6(b) A reusable surgical instrument—Class A.	Examples: scissors, artery forceps, tissue forceps, tissue clamps, excavators, osteotomes, chisels.
6(c) A surgically invasive device for transient use to supply energy in form of ionising radiation—Class C.	Examples: catheters containing or incorporating radioactive isotopes where the isotope is not intended to be released into the body.
6(d) A surgically invasive device for transient use to have a biological effect or be wholly or mainly absorbed—Class C.	Where the biological effect is an intended one rather than unintentional. e.g. bone wax "Absorption" refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body This rule does not apply for substances that are excreted without modification from the body *i.e.* insufflation gases for the abdominal cavity
6(e) A surgically invasive device for transient use to administer medicine via a delivery system, and where the administration is potentially hazardous to the patient—Class C.	Devices for repeated self-application where the dose and the medicine are critical. Examples: personal insulin injectors (commonly referred to as 'pens').
6(f) Surgically invasive device intended for use in direct contact with the central nervous system – Class D	
6(g) Surgically invasive device for transient use to diagnose, monitor, control or correct a defect of the heart, or central circulatory system through direct contact—Class D.	Examples: cardiovascular catheters, angioplasty balloon catheters, coronary artery probes.

RULE 7: SURGICALLY INVASIVE DEVICES INTENDED FOR SHORT-TERM USE

This rule covers devices to be used continuously for at least 60 minutes but not more than 30 days and are used in the context of surgery or post-operative care (for example, clamps and drains), infusion devices (cannulae and needles) and catheters of various types.

Rule 7	Description
7(a) Surgically invasive device for short-term use—Class B.	Examples: clamps, infusion cannulae, skin closure devices or temporary filling materials, some surgical retractors for example, chest retractors for cardiac surgery.
7(b) A surgically invasive device for short-term use to administer medicine - Class C.	Examples: intravenous cannulae.
7(c) A surgically invasive device for short-term use to undergo a chemical change in a patient's body (except a device intended to be placed in the teeth) - Class C.	Examples: surgical / tissue adhesives.
7(d) A surgically invasive device for short-term use to supply energy in the form of ionising radiation - Class C.	Examples: bradytherapy devices.
7(e) A surgically invasive device for short-term use to have biological effect—Class D.	Examples: haemostatic sponge.
7(f) A surgically invasive device for short-term use to be wholly, or mostly, absorbed by a patient's body—Class D.	Examples: absorbable sutures.
7(g) A surgically invasive device for short-term use to be used in direct contact with the central nervous system—Class D.	Examples: neurological catheters, cortical electrodes, connonoid paddles.
7(h) A surgically invasive device for short-term use to be specifically used to diagnose, monitor, control or correct a defect of the heart, or central circulatory system, through direct contact with these parts of the body—Class D.	Examples: cardiovascular catheters, cardiac output probes and temporary pacemaker leads, thoracic catheters intended to drain the heart, including the pericardium and a carotid artery shunt.
7(i) A surgically invasive device for short-term use that is intended by the manufacturer to be placed in the teeth and to undergo a chemical change in the body—Class B. *Note: for this clause, a medical device to be placed in the teeth includes a device that is intended to penetrate a tooth but that does not enter the gum or bone beyond the tooth.*	Examples: dental adhesives used for root canal therapy.

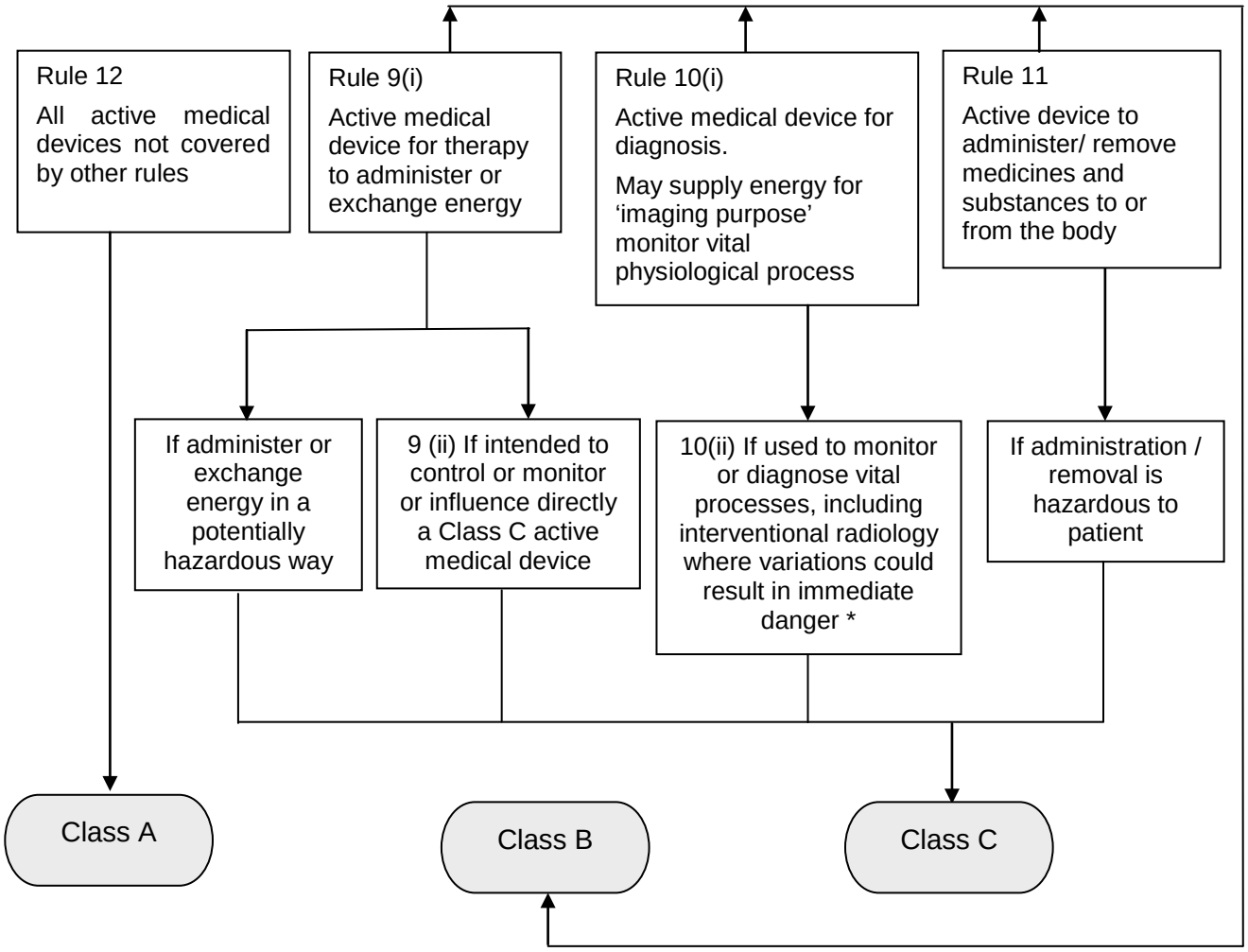
RULE 8: SURGICALLY INVASIVE DEVICES FOR LONG-TERM USE AND IMPLANTABLE DEVICES

Devices covered by this rule include implants used in orthopaedic, dental, ophthalmic and cardiovascular fields. In addition, soft tissue implants used in plastic surgery are covered by this rule.

Rule 8	Description
8(a) All implantable devices and surgically invasive devices for long-term use and implantable devices—Class C.	Examples: implantable joint replacements, shunts, stents, nails, plates and screws, intra-ocular lenses, infusion ports, peripheral vascular grafts, bone cements, maxillo-facial implants.
8(b) A surgically invasive device for long-term use to be placed in the teeth—Class B.	Examples: bridges and crowns.
8(c) A surgically invasive device for long-term use to be used in direct contact with the heart, the central circulatory system or the central nervous system—Class D.	Examples: prosthetic heart valves, aneurysm clips, vascular prostheses, spinal stents, vascular stents, CNS electrodes, cardiovascular sutures.
8(d) A surgically invasive device intended to be life supporting or life sustaining—Class D	Example: pacemakers
8(e) A surgically invasive device intended to be active implantable medical device—Class D	
8(f) An *implantable* accessory to an active implantable medical device—Class D.	Example: electrode leads associated with pacemakers, defibrillators, nerve stimulators.
8(g) An active device to control, monitor or directly influence the performance of an active implantable medical device—Class D.	Example: clinician's programming device for pacemakers, patient control device for nerve stimulation devices.
8(h) A surgically invasive device for long-term use intended by the manufacturer to have a biological effect—Class D.	Implants claimed to be bioactive (Hydroxyapatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer)
8(i) A surgically invasive device for long-term use to be wholly, or mostly, absorbed by a patient's body—Class D.	Examples: absorbable sutures, bioactive adhesives and implants through the attachment of surface coatings such as phosphorylcholine.
8(j) A surgically invasive device for long-term use to administer medicine—Class D.	Examples: rechargeable non-active drug delivery systems.
8(k) A surgically invasive device for long-term use to undergo a chemical change in the patient's body (except a device that is to be placed in the teeth)—Class D.	Examples: surgical adhesive.
8(l) Breast Implants – Class D	
8(m) A surgically invasive device for long-term use that is intended by the manufacturer to be placed in the teeth and to undergo a chemical change in the body is Class B. *Note: for this rule a medical device to be placed in the teeth includes a device that is intended to penetrate a tooth but does not enter the gum or bone beyond the tooth.*	Examples: dentine adhesives.

3.8.3 Active medical devices

This flowchart is a summary of the rules described in the Technical Rules for Classification of Medical Devices



**Note: Rule 10(i) also includes a device that is intended to emit ionising radiation and to be used for diagnostic or therapeutic interventional radiology; or a device that is intended to be used to control or monitor, or directly influence, the performance of a device that emits ionising radiation and used for diagnostic or therapeutic interventional radiology.*

An active medical device is defined in the General Regulations to the Medicines Act as being a medical device that is intended by the manufacturer:

- to depend on its operation on a source of electrical energy or other source of energy (other than a source of energy generated directly by a human being or gravity); and
- to act by converting this energy; but
- does not include a medical device that is intended by the manufacturer to transmit energy, a substance, or any other element, between an active medical device and a human being without any significant change in the energy, substance or other element being transmitted.

RULE 9: ACTIVE MEDICAL DEVICES FOR THERAPY

Active medical device for therapy means an active medical device that is intended by the manufacturer to be used on a human being, either alone or in combination with another medical device, to support, modify, replace or restore biological functions or structures for the purpose of treating or alleviating an illness, injury or disability.

This rule covers devices that are electrical equipment used in surgery, devices used in specialised treatments and stimulation devices.

Rule 9	Description
9 (i)(a) An active medical device for therapy to administer energy to a patient, or exchange energy to or from a patient—Class B.	Examples: electrical—magnetic and electromagnetic energy muscle stimulators, external bone growth stimulators, TENS devices, electrical acupuncture thermal energy—cryosurgery equipment, heat exchangers mechanical energy—powered dermatomes, drills and dental hand pieces light—phototherapy for skin treatment and for neonatal care sound—hearing aids.
9 (i)(b) An active device to administer or exchange energy in a potentially hazardous way, having regard to the nature, density and site of application of the energy—Class C. (*The term "potentially hazardous" refers to the type of technology involved and the intended application)*	Examples: kinetic energy—lung ventilators thermal energy—infant incubators, warming blankets for unconscious patients, blood warmers, heat exchangers used in intensive care electrical energy—high-frequency electrosurgical generators, electrocautery, external defibrillators, electroconvulsive therapy equipment coherent light—surgical lasers ultrasound—lithotriptors, physiotherapy ultrasound devices ionising radiation—radioactive sources for after-loading therapy, therapeutic cyclotrons, linear accelerators, therapeutic X-ray sources.
9(ii) An active device to control or monitor, or directly influence the performance of an active medical device for therapy of the kind in the previous entry—Class C.	Examples: external feedback systems for active therapeutic devices, after-loading control devices.

RULE 10: ACTIVE MEDICAL DEVICES FOR DIAGNOSIS

Active medical device for diagnosis means an active medical device that is intended by the manufacturer to be used on a human being, either alone or in combination with another medical device, to supply information for the purpose of detecting, diagnosing, monitoring or treating physiological conditions, states of health, illness or congenital deformities.

This rule covers devices that are used in ultrasound diagnosis and capture of physiological signals and devices used in diagnostic radiology.

Note: Active devices for diagnosis are classified as Class A, in accordance with Rule 12, unless they are specifically covered by any of the clauses in Rules 9, 10 or 11.

Rule 10	Description
10(i)(a) A device to supply energy that will be absorbed by a patient's body (except a device that illuminates the patient's body in the visible spectrum)—Class B.	Examples: magnetic resonance equipment, pulp testers, evoked response stimulators, diagnostic ultrasound.
10(i)(b) A device to be used to image in vivo distribution of radiopharmaceuticals in patients—Class B.	Examples: gamma cameras, positron emission tomography, single photon emission computer tomography.
10(i)(c) A device used for direct diagnosis or monitoring of vital physiological processes of a patient, excluding devices mentioned in the previous entry—Class B.	Examples: electrocardiographs, electroencephalographs, cardioscopes with or without pacing pulse indicators, electronic thermometers.
10(i)(d) A device to diagnose and or monitor vital physiological parameters of a patient, and the nature of variations monitored could result in immediate danger to the patient—Class C. *Note: For this clause 'variations monitored', is taken to mean that the result of monitoring could lead to immediate danger to the patient. This is typically, but not always, accompanied by an alarm.*	Examples: intensive care monitoring systems, biological sensors, blood gas analysers used in open-heart surgery, cardioscopes and apnoea monitors including those in home care.
10(ii)(a) A device to emit ionising radiation and to be used for diagnostic or therapeutic interventional radiology—Class C.	Examples: diagnostic x-ray sources, linear accelerators.
10(ii)(b) A device to control, monitor or directly influence the performance of a device in the previous entry—Class C.	Examples: auto exposure control systems, radiotherapy afterloading controls systems.

RULE 11: ACTIVE MEDICAL DEVICES INTENDED TO ADMINISTER OR REMOVE MEDICINES, BODY LIQUIDS OR OTHER SUBSTANCES FROM A PATIENT'S BODY

This rule covers drug delivery systems and anaesthesia equipment.

Rule 11	Description
11 (a) An active device to administer or remove medicine, body liquids or other substances—Class B.	Examples: suction equipment, feeding pumps, jet injectors for vaccination.
11 (b) An active device to administer or remove medicine, body liquids or other substances in a way that is potentially hazardous to the patient, having regard to the substances, the part of the body concerned, and the characteristics of the device—Class C.	Examples: infusion pumps, ventilators, anaesthesia machines, anaesthetic vaporisers, dialysis equipment, blood pumps for heart-lung machines, hyperbaric chambers, pressure regulators for medical gases, medical gas mixers, moisture exchangers in breathing circuits, nebulisers where the failure to deliver the appropriate dosage form could be hazardous.

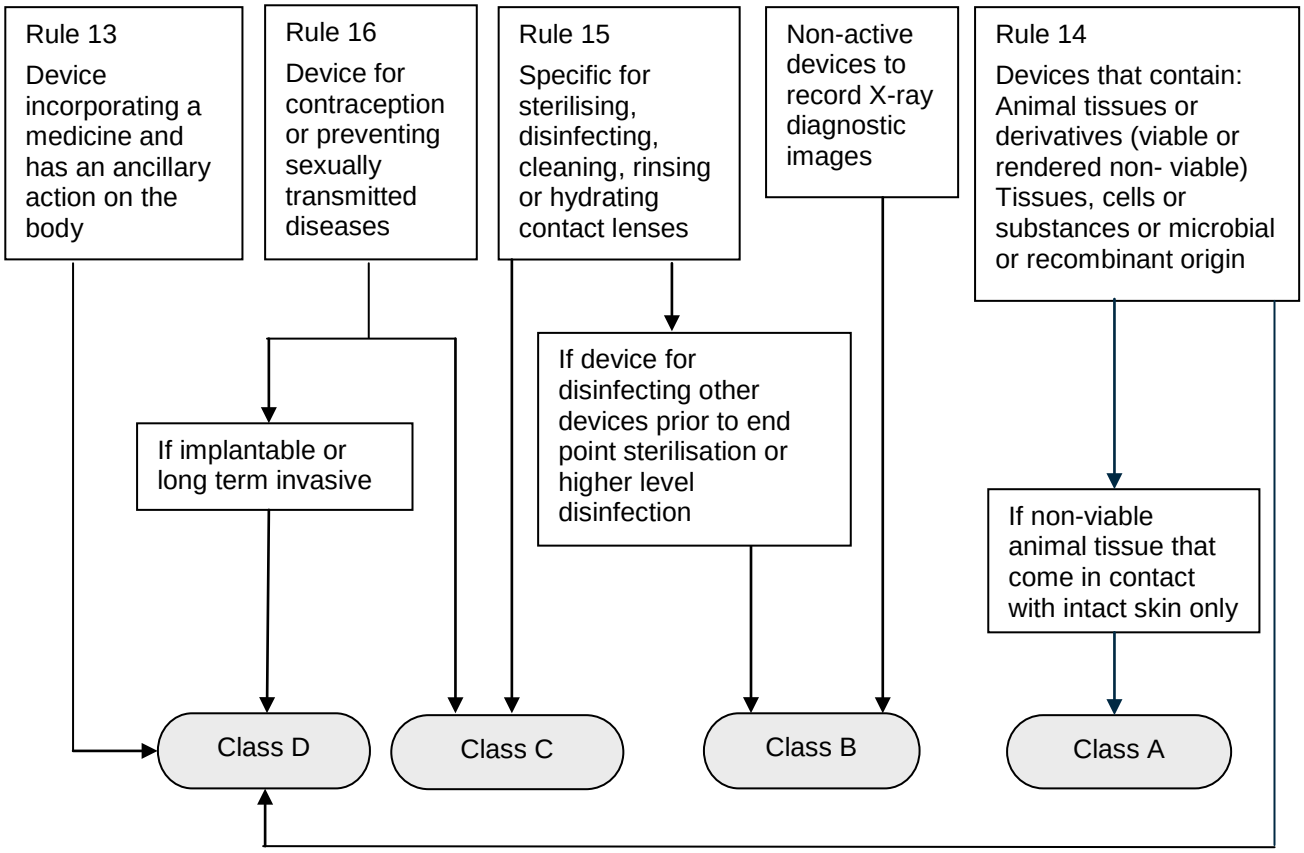
RULE 12: ACTIVE MEDICAL DEVICES—GENERAL

This rule applies to active medical devices that are not covered by a specific rule.

Rule 12	Description
An active device is Class A, unless the device is classified at a higher level under another rule.	Examples: examination lights, surgical microscopes, diagnostic devices for thermography, active devices for recording, processing or viewing of diagnostic images, dental curing lights.

3.8.4 Additional Classification Rules 13, 14, 15 & 16

This flowchart is a summary of the rules described in the Technical Rules for Classification of Medical Devices



RULE 13: DEVICES INCORPORATING A MEDICINE

This rule covers medical devices that incorporate a medicinal substance including stable derivatives of human blood and blood plasma that assists the function of the device.

Rule 13	Description
13 A device incorporating a substance that if used separately would be a medicine and has an ancillary action on the body—Class D.	Examples: antibiotic bone cements, condoms with spermicide, heparin-coated catheters, dressings incorporating an antimicrobial agent where the purpose of such an agent is to provide ancillary action on the wound.

RULE 14: DEVICES CONTAINING ANIMAL OR HUMAN CELLS / TISSUES OR DERIVATIVES, OR MICROBIAL OR RECOMBINANT TISSUES, CELLS OR SUBSTANCES

This rule covers devices that contain or are made of animal tissues that have been rendered non-viable or derivatives from such tissues also being non-viable, or microbial or recombinant tissues, cells or substances.

Rule 14	Description
14(a) Devices that contain animal or human cells or tissues or derivatives, whether viable or that have been rendered non-viable, are Class D. Devices that contain tissues, cells or substances of microbial or recombinant origin are Class D, even if the device is only intended to come into contact with intact skin.	Examples: biological heart valves, porcine xenograft dressings, catgut sutures, implants, dressings made from collagen. Examples: intra-ocular fluids, meniscule joint fluid replacement, anti-adhesion barriers, tissue fillers based on hyaluronic acid derived from bacterial fermentation processes.
14(b) Devices that only contains animal tissues that have been rendered non-viable and the device is only intended by the manufacturer to come into contact with intact skin – Class A	Examples: leather straps associated with limb prostheses.

RULE 15: DEVICES INTENDED FOR STERILISING, DISINFECTING, CLEANING, RINSING ETC

This rule covers various contact lens fluids and substances or equipment to disinfect another medical device. It does not cover devices that clean by a physical action only.

Rule 15	Description
15(a) A device specifically for sterilising medical devices, or disinfecting as the end point of processing - Class C.	Examples: hard contact lens solutions, comfort solutions.
15(b) A device intended for disinfecting medical devices prior to end point sterilisation or higher level disinfection – Class B	Examples: disinfectants for haemodialysis devices or endoscopes, sterilisers to sterilise medical devices, washer disinfectors.
15(c) A device specifically for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses - Class C. *Note: this clause does not apply to a medical device that is intended only to clean another medical device (other than contact lenses) by means of physical action—these devices are Class A.*	

RULE 16: DEVICES FOR CONTRACEPTION OR PREVENTION OF SEXUALLY TRANSMITTED DISEASES

Some devices covered by this rule may perform both functions, for example, condoms.

Rule 16	Description
16 (a) A device for contraception or the prevention of sexually transmitted diseases—Class C.	Examples: condoms, contraceptive diaphragms.
16 (b) An implantable or invasive device for long-term use—Class D.	Examples: contraceptive intrauterine devices (IUDs), surgically implanted contraceptive devices.

3.8.5 Classification examples

The following examples are provided to demonstrate the importance of considering all the Classification Rules for a device to ensure that the device is appropriately classified. The examples will not include all the possible devices that may be on the market - they are intended to demonstrate how different variables affect the classification of a device. There may be several Classification Rules that apply to a device - if this happens the higher classification applies.

Warming Blanket

Intended purpose: To re-warm patients who are cold (hypothermic or recovering post-surgery). These patients may be unconscious.

Description	Variable/comments	Classification Rule	Classification
A large piece of fabric material blanket specially designed to keep a person warm and/or to prevent the further loss of body heat, often in an emergency situation	Not powered	Rule 1	Class A
Blanket used to blow warm air onto patient in hypothermia, post-surgery, (person unable to regulate own body temperature)	Electrically powered Potentially hazardous as patient may get burned or overheated; may have peripheral neuropathy (so not able to feel the intensity of the heat), may not be able to indicate if the blanket is too hot (e.g. neonates, unconscious patients). If a patient's blood pressure is critically low when the therapy is first applied, the applied heat may be detrimental to maintaining adequate blood pressure, as resulting vasodilation reduces blood pressure	Rule 9 (i) (b)	Class C

Nebuliser

Intended purpose: To deliver particles of medication/moisture (typically bronchodilators such as salbutamol) to the airways and lungs.

Description	Variable/comments	Classification Rule	Classification
A compressor that pumps compressed air through the fluid to be nebulised, thus forming droplets/vapour and carrying this into the airways during inspiration	Electrically powered	Rule 9(i)(a)	Class B
A fast-track nebuliser is able to nebulise more fluid per minute, and with finer droplets that reach more deeply into the lungs	Electrically powered—delivers medication in a more potent form than a standard nebuliser and the administration of medicine at an incorrect rate can be life threatening	Rule 9(i)(b)	Class C

Dressings

Intended purpose: To be applied to a wound in order to promote healing and/or prevent further harm.

Description	Variable/comments	Classification Rule	Classification
Adhesive dressing strip—not sterile	Not sterile	Rule 1(a)	Class A
Adhesive dressing strip—sterile	Sterile	Rule 1(b)	Class B
Adhesive dressing strip—with silver	Has silver (microbial agent) to assist in healing. The silver is a medicine	Rule 13	Class D
Compression bandage used for sprains	Used for compression to assist in injury management	Rule 1(a)	Class A
A wound dressing for deep wounds and ulcers that have breached the dermis containing alginate to absorb exudate	Contains alginate of microbial origin	Rule 14	Class D
A wound dressing for deep wounds and ulcers that have breached the dermis containing alginate to absorb exudate	Contains alginate of non-microbial origin. Heals by secondary intent	Rule 1 (c)	Class C
A wound dressing including materials of biological origin, such as collagen, sodium hyaluronate, chondroitin sulphate	Contains materials of biological origin	Rule 14	Class D

Description	Variable/comments	Classification Rule	Classification
A non-sterile, trauma covering used to maintain the stability of a burn patient *en route* to a hospital. Dressing is coated in a gel containing anaesthetic	Contains medicine	Rule 13	Class D
A non-sterile, trauma covering used to maintain the stability of a full thickness burn patient *en route* to a hospital. Dressing is coated in a gel that does not contain any active medicine ingredients	Breached the dermis. Does not contain medicine	Rule 1(c)	Class C

Fixation Screws

Intended purpose: To hold plates or nails to bone, fasten soft tissue to bone or provide interfragmentary stabilisation for bone.

Description	Variable/comments	Classification Rule	Classification
Metal fixation screw; permanent implant	Permanently implanted	Rule 8	Class C
Metal fixation screw—used to hold bone together for up to 30 days (for example, to support healing of a fracture)	Short-term use	Rule 7	Class B
Metal fixation screw—used to hold bone together temporarily during surgery	Transient use	Rule 6	Class B
Absorbable fixation screw; permanent implant, absorbed into body	Will be absorbed into body	Rule 8	Class D
Fixation screw that has direct contact with central circulatory or central nervous systems	Location in body - direct contact with high-risk areas (central circulatory or central nervous systems).	Rule 8	Class D

4 CLASSIFICATION OF IVD MEDICAL DEVICES

4.1 OVERVIEW

The medical devices regulatory framework has a classification system for medical devices and IVDs, as per Medical Device Regulation 12 of Act 101 of 1965.

A medical device, other than an IVD medical device, has the medical device classification applying under the classification rules set out in the Technical Rules for Classification of Medical Devices.

An IVD medical device has the medical device classification applying under the classification rules set out in the Technical Rules for Classification of IVDs.

The classification levels for IVDs are:

Classification	Level of risk
Class A	no public health risk or low personal risk
Class B	low public health risk or moderate personal risk
Class C	moderate public health risk or high personal risk
Class D	high public health risk

The same classification rules apply to both commercial IVDs and in-house IVDs.

The manufacturer or distributor is responsible for determining the class of a device using a set of classification rules with regard to:

- the manufacturer's intended use of the device; and
- the level of risk to the patient and the public (taking into account the likelihood of harm and the severity of that harm).

Identical devices may be classified differently if they are to be used for different diagnostic purposes. This is why the manufacturer's intended use of the device is critical to determining the appropriate class. The intended use can be obtained from the:

- Information provided with the IVD (including Instructions for Use and labelling)
- Advertising materials
- Design dossier (if applicable).

Note: There may be medical devices or IVDs where the classification in South Africa is different to the classification in other countries. The applicant should take into account the South African requirements when determining the classification of a device that is to be supplied in South Africa.

4.2 PRINCIPLES FOR APPLYING THE CLASSIFICATION RULES

The classification rules are based on the manufacturer's intended purpose, taking into account the degree of risk involved to the patient and the public. The classification must be consistent with the information accompanying the IVD including the labels, Instructions for Use, brochures and operating manuals. If the intended purpose of the device is not clear, the Council will request further clarification from the manufacturer and may also consider the purpose generally accepted in clinical and laboratory practice.

All the classification rules must be considered to determine the classification of the IVD. In some cases, more than one classification rule may be applicable to an IVD, but if this occurs the higher risk classification applies. There are exceptions to this principle, whereby a number of the classification rules state that despite certain other rules, a particular risk classification should always apply to a type of IVD. These include for example Rule 1.5 which specifies that IVDs that are non assay-specific quality control material are Class B IVDs.

A number of IVDs are supplied with, or are required to be used in combination with, other IVDs, non-IVD medical devices or accessories to medical devices. The classification rules must be applied separately to each device. An accessory to an IVD is described as an item that its manufacturer specifically intends to be used together with an IVD, to enable that IVD to be used as intended. Accessories are classified independently of the IVD that they are to be used with.

Materials that are intended to be used for the calibration or quality control of a particular named assay are considered to be part of a single assay with a common intended purpose. Therefore they have the same risk classification as each of the other assay components based on the common intended purpose of the assay, even if these materials are sold separately.

If one or more IVDs are supplied as part of a system or a procedure pack, the class for the entire pack is the highest class of any individual IVD in the pack. For example, if a procedure pack contains a selection of Class A, B and C IVDs, then the entire pack is classified as a Class C IVD.

If a procedure pack contains a mixture of IVDs and non-IVD medical devices, the individual component of the highest Class will determine the overall classification of the procedure pack. The individual device of the highest Class will also determine if the procedure pack is to be included in the IVD Register as an IVD medical device or a non-IVD medical device. For example, a procedure pack contains a portable prothrombin time meter (Class A IVD), test strips or cartridges for prothrombin time self-testing (Class C IVD), and a lancet (Class B medical device) for obtaining a blood specimen. The procedure pack would take on the highest classification assigned to any individual component, namely Class C IVD, and is required to be included in the IVD Register as an IVD medical device.

When an IVD and a medical device within a procedure pack are of the same classification level (equivalent risk class) the primary intended purpose of the device is to be considered to determine whether the pack is included on the Register as an IVD or a medical device. Where components of a procedure pack are also supplied separately, they need to be separately included in the Register e.g. Medical devices such as lancets.

In the event of a dispute between the manufacturer and the conformity assessment body concerned, resulting from application of the classification rules, the Council shall determine the classification.

4.2 Principles for applying the Classification Rules - continued

Software:

- that fits the definition of a medical device is also an active medical device since it relies on an energy source for its operation
- that is intended to make a device operate, control a device, or influence the functions of a device generally falls in the same classification as the device
- intended as an accessory to a medical device should be classified separately from the device with which it is used
- is considered an accessory when it is not essential to the operation of the device.

4.3 CLASSIFICATION RULES FOR IVDS

4.3.1 Classification Rule 1 - Detection of transmissible agents posing a high public health risk

An IVD medical device intended to be used for any of the following purposes is classified as a Class D IVD medical device:

a) to detect the presence of, or exposure to, transmissible agents in blood, blood components, blood products, cells, tissues or organs or any derivatives of these products of human or animal origin, in order to assess their suitability for transfusion or transplantation;

b) to detect the presence of, or exposure to, a transmissible agent that causes a serious disease with a high risk of propagation.

Rationale: Devices captured by this rule pose a high public health risk.

Rule 1 is presented in two parts:

Paragraph 1 (a) describes IVDs that are used to establish the safety of blood and blood components for transfusion, or cells, tissues and organs for transplantation. In most cases, the result of the test is a major determinant as to whether the donation or product will be used.

Paragraph 1 (b) describes IVDs that are used to diagnose clinical infections that cause serious diseases with a high risk of transmission from person to person in the population.

Serious diseases are those:

- that may result in death or long-term disability; and
- that are often incurable or require major therapeutic interventions; and
- where an accurate diagnosis is of vital importance to mitigate the public health impact of the condition.

Rule 1 applies to all assays used to determine suitability for transfusion or transplantation as part of the laboratory's infectious disease testing algorithm, and includes front-line or screening assays, confirmatory assays, supplemental assays, and IVDs that detect structural components or surrogate markers of transmissible agents that cause serious disease.

Some IVDs are intended only to be used in a diagnostic setting but are identical to those intended to be used for screening blood and tissue donations. These IVDs may be classified according to other rules if Rule 1(b) does not also apply, provided the Sponsor can provide assurance that the IVD is marketed in accordance with the alternate classification. For example, a syphilis assay can be classified as a Class D IVD if it is intended to screen blood and tissue donations, but is a Class C IVD as per rule 3(1)(a) if it is intended for diagnostic purposes only.

4.3.1 Classification Rule 1 - Detection of transmissible agents posing a high public health risk - continued

Examples

All tests used by the Blood Service for testing of the blood supply are Class D IVDs, including screening and confirmatory assays for human immunodeficiency virus (HIV), Hepatitis C virus (HCV), Hepatitis B virus, HTLV I/II and syphilis. Any additional assays that are performed on a supplementary basis, such as those use to determine Cytomegalovirus status or suitability for Zoster immunoglobulin production, are also Class D IVDs.

All tests used by hospital-based laboratories that screen for infectious disease markers to determine suitability for organ or tissue transplantation under the requirements of their licence are Class D IVDs, including screening and confirmatory assays for HIV, HCV, Hepatitis B virus, HTLV I/II and syphilis.

Pyrogenicity tests (endotoxin activity assays) marketed for detection of bacterial contamination of blood components are Class D IVDs if the result of the test is a determinant as to whether or not the product will be used. By contrast, if the test is used for quality control purposes to measure the rate of contamination in a sample of products as part of the manufacturing process, then the test would be considered a manufacturing step and not an IVD.

All assays for the clinical diagnosis of infection by HIV 1 & 2, Hepatitis C virus, Hepatitis B virus and HTLV I/II are Class D IVDs. Assays for the clinical diagnosis of Hepatitis B virus are taken to include the following infectious disease markers: Hepatitis B surface antigen (HBsAg), Hepatitis B core IgM antibodies (anti-HBcore IgM), Hepatitis B core total antibodies (anti-HBcore tot) and Hepatitis B virus nucleic acid detection (HBV NAT).

Tests for detection of severe acute respiratory syndrome-associated coronavirus (SARS-CoV), highly virulent pandemic influenza, Variola virus (Smallpox virus) and viral haemorrhagic fevers such as Ebola virus or Marburg virus are Class D IVDs.

4.3.2 Classification Rule 2 - Detection of red blood cell antigens and antibodies and non red cell typing

(1) An IVD medical device is classified as a Class C IVD medical device if:

a) The device is intended to be used for detection of biological markers in order to assess the immunological compatibility of blood, blood components, blood products, cells, tissues or organs that are intended for transfusion or transplantation; and

b) The device is not one of the devices mentioned in subclause (2).

(2) An IVD medical device intended to detect the following markers is classified as a Class D IVD medical device:

a) ABO system - ABO1 (A), ABO2 (B), ABO3 (AB);

b) Rhesus system - RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e);

c) Kell system - KEL1 (K);

d) Kidd system - JK1 (Jka), JK2 (Jkb); and

e) Duffy system - FY1 (Fya), FY2 (Fyb).

4.3.2 Classification Rule 2 - Detection of red blood cell antigens and antibodies and non red cell typing - continued

Rationale

Devices captured by this rule present a high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation.

Classification rule 2 divides blood grouping IVDs into two subsets depending on the nature of the blood group antigen the IVD is designed to detect, and its importance in a transfusion setting. Essentially, all IVDs for testing for antigens or antibodies for any of the red blood cell markers not specifically mentioned in Rule 2 (2), and all IVDs used in tissue typing to test for human leukocyte antigens and antibodies, are Class C IVDs. The red blood cell markers captured by rule 2 (2) are critical to ensuring safe transfusion of blood and blood components, or transplantation of cells, tissues and organs, and are Class D IVDs.

Examples:

IVDs for testing for red blood cell antigens or antibodies from Blood Group A, Blood Group B, or Blood Group AB, within the ABO blood group system are Class D IVDs.

IVDs for testing for red blood cell antigens or antibodies for Cw or V from the Rhesus system; Cellano (k) from the Kell blood group system; or any markers from MNS or Cartwright blood group systems are Class C IVDs.

All IVDs used in tissue typing, to detect antigens and antibodies for any human leukocyte antigens are Class C IVDs.

4.3.3 Classification Rule 3 - Detection of transmissible agents or biological characteristics posing a moderate public health risk or a high personal risk

(1) An IVD is classified as Class C IVD medical devices if it is intended for any of the following uses:

a) detecting the presence of, or exposure to, a sexually transmitted agent;

b) detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation;

c) detecting the presence of an infectious agent where there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested;

d) pre-natal screening of women in order to determine their immune status towards transmissible agents;

e) determining infective disease status or immune status where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient;

f) the selection of patients;

i. for selective therapy and management; or
ii. for disease staging; or
iii. in the diagnosis of cancer;

g) human genetic testing;

4.3.3 Classification Rule 3 - Detection of transmissible agents or biological characteristics posing a moderate public health risk or a high personal risk - continued

h) to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient;

i) the management of patients suffering from a life-threatening infectious disease;

j) screening for congenital disorders in the foetus.

Note: For paragraph (f) an IVD medical device would fall into Class B under clause 1.5 if:

k) a therapy decision would usually be made only after further investigation; or

l) the device is used for monitoring.

(2) Despite subsection (1) an IVD is classified as a Class C IVD medical device if it is used to test for transmissible agents included in the list of Notifiable conditions as published from time to time.

(3) Rationale

IVDs captured by this rule present a moderate public health risk or a high individual risk, where an erroneous result could lead to a patient management decision resulting in a significant impact on patient outcome. These IVDs usually provide the critical or sole determinant for correct diagnosis.

The Department of Health publishes a list of diseases that are required to be notified nationally.

A case definition is provided for each disease or disease group and a number of the case definitions rely on laboratory definitive evidence, laboratory suggestive evidence, clinical evidence (probable cases), or a combination of various markers to be present to require their notification. Contribution to the diagnosis of a particular disease through the results of testing for any of the markers mentioned as either suggestive or definitive evidence, are taken to be Class C IVDs. Where information presented in the Instructions for Use for a particular assay represents that an additional marker (beyond those specified in the case definitions) may also be used to diagnose a notifiable disease, these too are taken to be Class C IVDs.

IVDs that are used to detect the presence of, or exposure to, sexually transmitted agents are Class C IVDs. Tests for HIV, HCV and Hepatitis B virus and Tuberculosis, which are regarded as serious diseases (and are therefore Class D IVDs).

Examples:

- Tests to detect the presence or exposure to a sexually transmitted agent such as *C. trachomatis* or *N. gonorrhoea* are Class C3 IVDs. Antibodies to *C. trachomatis* may be used to indicate either current or previous infection and therefore are also regarded as a Class C IVD under Rule 3 (1) (a). Tests for the detection of *Chlamydia* species to the genus level and for *Chlamydia pneumonia* only are not captured by this rule, and would be regarded as Class B IVDs.
- IVDs used to detect in cerebrospinal fluid or blood, the presence of an infectious agent that has a risk of limited propagation include the following as Class C IVDs: tests for the direct detection of *N. gonorrhoea* or *Cryptococcus neoformans* antigens; tests for the detection of *Haemophilus influenza* type B (Hib) antigen; tests for the detection of IgM antibodies to malaria parasites.

4.3.3 Classification Rule 3 – Examples - continued

- Tests that are used to detect the presence of an infectious agent, whereby an erroneous result would cause death or severe disability to the individual or foetus being tested are Class C IVDs. This includes tests for emerging serious diseases such as Hendra virus, or tests to confirm the presence or identity of methicillin-resistant *Staphylococcus aureus* (MRSA), either directly from a clinical specimen or from a cultured isolate (note that microbiological culture media is a Class A IVD under Rule 7). This rule also applies to other serious infectious diseases such as prion diseases or malaria.
- Prenatal screening tests include a number of different analytes which together generate a testing profile for infections that may cause illness in pregnant women, and birth defects or serious infections in newborns. These tests are sometimes collectively referred to as a TORCH screen and are regarded as Class C IVDs. Tests usually include detection of antibodies to *Toxoplasma gondii*, *Rubella virus*, *Cytomegalovirus* (CMV), *Herpes simplex virus 1 & 2*, *Measles virus* and *Treponema pallidum*.
- Tests that are used to select patients for selective therapy and management are Class C IVDs and include viral genotyping assays to establish a suitable course of therapy, or Her2/neu testing to select patients with breast cancer for treatment using trastuzumab.
- Tests for tumour markers such as free prostate specific antigen (free PSA), or tests where results are expressed as a percentage or ratio against total PSA for use in differentiating between benign or malignant tumours are Class C IVDs.
- Rule 3(f) includes a note which describes tests where a therapy decision is only made after further investigation, or that are used for monitoring. Tests intended to be used for initial screening, such as a faecal occult blood screening test (FOBT) for bowel cancer, require further investigation if a positive result is obtained; and tests used only for monitoring disease status, such as a total PSA which may aid in the management of a prostate cancer patient are regarded as Class B IVDs under Rule 7.
- Pharmacogenetic tests to predict metabolism of warfarin, or tests for other cytochrome P450 oxidative enzymes which may be used to gauge the metabolism rate of drugs are Class C IVDs.
- All tests used for human genetic testing are Class C IVDs, for example tests for detecting the Philadelphia chromosome, Huntington's disease or cystic fibrosis.
- Tests for therapeutic monitoring of immunosuppressive medicines such as cyclosporin and tacrolimus are Class CIVDs, due to the impact of an erroneous result on a patient and the potential for adverse transplantation outcome. Other tests for monitoring substances or biological components that are regarded as Class C IVDs include acute cardiac markers such as Troponin I, Troponin T and CKMB.
- Class C IVDs used for the management of life-threatening infectious disease include viral load and genotyping assays for HIV and Hepatitis C virus.
- Class C IVDs used for screening for congenital disorders include pre- and post-natal tests for trisomy 13, trisomy 18, trisomy 21 or Klinefelter's syndrome; tests for alpha-fetoprotein (AFP) when used in the detection of foetal open neural tube defects.
- Software that is supplied as a "stand-alone" IVD, for use in the interpretation of a series of results obtained as part of a first trimester screening assessment, in order to determine foetal risk of trisomy 21 is a Class C IVD. Software that is supplied as a "stand-alone" IVD, for use in staging or predicting severity of disease by means of an algorithm based on a combination of anthropometric measures and non-invasive biomarkers is a Class C IVD.

4.3.4 Classification Rule 4 - IVD medical devices for self-testing

An IVD medical device for self-testing is classified as a Class C IVD medical device unless:

a) the result of the examination is not determining a serious condition, ailment, or defect; or

b) the examination is preliminary and follow-up additional testing is required.

Rationale

Self-testing IVDs are intended to be used by individuals with no scientific or technical expertise, or formal training in a medical field or discipline to which the test relates. Self-test devices can pose a low, moderate or high personal risk and can therefore fall into Class A, B or C.

The definition of ***IVD medical device for self-testing*** as prescribed under regulation includes IVDs intended for use in the collection of a sample by a lay person and, if the sample is tested by another person (e.g. a laboratory) the results are returned directly to the person from whom the sample was taken without the direct supervision of a health professional who has formal training in a medical field or discipline to which the test relates. The Council interprets 'direct supervision' to mean written or verbal communication from a health professional who is personally treating the person and therefore has already established a professional relationship with their client, or verbal communication with the person by a health professional who is able to explain the significance of the test and answer questions that the person may have regarding the interpretation of the result. This applies regardless of the nature of the result, e.g. positive, negative, quantitative value.

Rule 4 classifies IVDs for self-testing as Class C IVDs if the condition, ailment or defect to which the test relates is generally considered to be:

- inappropriate to be diagnosed or treated without consulting a health professional
- beyond the ability of the average person to evaluate accurately, or be treated for safely without adequate supervision.

In situations where use of the self test does not determine a serious condition or the result is purely preliminary, other classification rules apply. For example a positive result from a pregnancy self-test kit will generally be followed up with a visit to the user's medical practitioner therefore a pregnancy self test kit is not regarded as a Class C IVD, rather it is classified as a Class B IVD using rule 7.

Examples

- System for self-monitoring of blood glucose - Class C IVD. Each of the individual components of a self-testing blood glucose monitoring system is classified individually, with the highest overall class applying to the system. So a glucose meter, as an instrument for *in vitro* diagnostic procedures, is classified as a Class A IVD as per rule 6, the glucose reagent test strips for use in self-testing are classified as Class C IVDs since an erroneous result obtained when self-testing for blood glucose may lead to a life-threatening situation and the lancet for obtaining a blood sample is classified as a Class B medical device. As a system intended for self-testing, a glucose meter, glucose reagent test strips and lancet would be classified as a Class C IVD.
- Urine self-test strips to detect glucose and other general urine chemistry analytes - Class B IVD.
- Pregnancy and fertility self-testing kits - Class B IVD.

4.3.5 Classification Rule 5 - Non assay-specific quality control material

Despite rules 1 to 4, an IVD medical device that is intended to be used as non assay-specific quality control material is classified as a Class B IVD medical device.

Rationale

Devices in this class pose a low public health risk or moderate personal risk.

Quality control material is taken to be controls, calibrators and standards, and as a subset of this, non assay-specific quality control materials are those that are not assigned for use with a specific assay.

This rule does not apply to quality control materials that are assigned for use with a specific assay, or where the manufacturer of the quality control material has provided detailed information (e.g. references ranges) relating to a particular assay - these are taken to be the same risk class as the parent assay based on the common intended purpose, even if they are sold separately.

Examples

- Non-assay specific control plasmas for use in coagulation studies.
- Non-assay specific control serum containing multiple biochemical analytes.
- Non-assay specific control serum, for use as an independent control for HCV antibody assays.
- A DNA or RNA probe supplied for use as a non-assay specific control for in situ hybridisation of targeted gene polymorphisms. Although an ISH probe is intended for use in human genetic testing and could therefore be regarded as a Class C IVD, under rule 5 despite any other classification rule, non-assay specific quality control material is a Class B IVD.

4.3.6 Classification Rule 6 - Reagents, instruments etc.

(1) A reagent or other article that possesses specific characteristics, intended by the manufacturer, to make it suitable for *in vitro* diagnostic procedures related to a specific examination is classified as a Class A IVD medical devices.

(2) Despite rules 1 to 5, the following IVD medical devices are classified as Class A IVD medical devices

a) an instrument, intended by the manufacturer, specifically to be used for *in vitro* diagnostic procedures;

b) a specimen receptacle;

c) a microbiological culture medium.

In this clause:

"examination" means a set of operations having the object of determining the value or characteristics of a property.

Note 1. In some disciplines (for example, microbiology) an examination is the combination of a number of tests, observations or measurements.

"specimen receptacle" means a device, whether vacuum-type or not, specifically intended by its manufacturer for the primary containment and preservation of a specimen derived from the human body for the purpose *of in vitro* diagnostic examination.

4.3.6 Classification Rule 6 - Reagents, instruments etc. – continued

Note 1. A specimen receptacle is considered to be an *in vitro* diagnostic device.

Note 2. A product for general laboratory use is not an *in vitro* diagnostic medical device unless the product, in view of its characteristics, is specifically intended by its manufacturer to be used for *in vitro* diagnostic examination.

Rationale

Devices captured by this rule present a low individual risk and minimal or no public health risk.

Products for general laboratory use are not IVD medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination. For example, pipettes, test tubes and general consumables which are not specifically intended by the manufacturer to be used to perform a particular test are not considered IVD medical devices.

Stains are generally considered to be IVDs if they are intended by the manufacturer to be for a diagnostic purpose. Single staining solutions for diagnostic use are classified as Class A IVDs under rule 6 (1) **only if** they are supplied separately and without instructions on how to perform a particular staining procedure, because they are regarded as general purpose reagents. If staining solutions are supplied either individually or as a kit, together with instructions linking that stain to a particular staining process, the staining solution or kit must be classified according to the overall intended purpose of the stain.

Stain powders or base ingredients used to prepare stains for use in a diagnostic setting are not considered to be IVDs because they are not finished products. However, once a powder or base ingredients have been made into a stain by a laboratory, the finished staining solution/s would be regarded as an IVD and an appropriate risk classification applied according to the overall intended purpose of the stain.

Due to their interdependence, an instrument or software that is specifically required to be used to perform a particular test will be assessed at the same time as the test kit even though the instrument itself is classified as Class A IVD.

Examples

- Grams iodine solution which is individually supplied by a manufacturer without specific instructions for use in a Gram staining procedure is a Class A IVD because it may be used in multiple disciplines (e.g. Clinical microbiology, histology, cytology).

  Conversely, a foetal cell staining kit, supplied with instructions for performing a Kleihauer stain to identify candidates required to receive more than one dose of anti-D immunoglobulin is a Class B IVD under rule 7.

  A ready-to-use Romanowski staining kit supplied for use in haematology for staining peripheral blood smears to perform white cell differentiation and evaluation of red cell morphology is also a Class B IVD under rule 7.

- A separately supplied reagent labelled as intended for use with a specific microbial identification testing kit, in order to determine the biochemical identification of a clinical isolate is a Class B IVD, in line with the classification of the microbial identification IVD, e.g. 3 % hydrogen peroxide for use in a catalase test or tetramethyl-p-phenylenediamine (TMPD) for use in an oxidase test.

4.3.6 Classification Rule 6 - Reagents, instruments etc. – continued

Conversely, a general reagent labelled simply as 3 % hydrogen peroxide or TMPD, which is not manufactured and supplied specifically for *in vitro* diagnostic use, is not considered to be an IVD.

- Microscope counting chambers such as haemocytometers and chambered urinalysis slides labelled as being intended for the microscopic examination of urine and other body fluids are Class A IVDs because they are suitable for use across multiple disciplines or in several different diagnostic applications. Plain ground-glass microscope slides, although intended for an application related to microscopic analysis, are not generally intended to be used expressly as an IVD medical device.
- Except for specimen containers intended for use in self testing, evacuated or non-evacuated blood collection tubes, and specimen containers intended for the collection of urine, faeces, cell or tissue specimens for subsequent *in vitro* examination are Class A IVDs. General laboratory tubes that are used to contain reactions or to contain and store processed specimens are not considered to be specimen receptacles.
- Manual, automated or semi-automated instruments such as an enzyme immunoassay analyser, an ESR analyser, or a thermal cycler for performing nucleic acid amplification in a clinical specimen are Class A IVDs.
- General laboratory equipment such as waterbaths, centrifuges, balances and automatic pipettes are not considered to be IVDs unless they are specifically intended by the manufacturer (in product labelling or accompanying literature) to be used for an *in vitro* diagnostic examination e.g. blood bank tube centrifuge for spinning of blood grouping reactions.
- Prepared (ready to use) microbiological culture media, including agar containing selecting agents, antimicrobials, chromogenic agents or chemical indicators for colony differentiation are Class A IVDs. Dehydrated powders and agar bases are not considered to be IVDs.
- Class A IVD General Laboratory reagents are those that are suitable for use across multiple disciplines or a broad range of different purposes. Standard buffers (e.g. PBS) and saline solutions are not considered to be an IVD unless supplied specifically for use as an IVD.
- Non-assay specific instrument consumable reagents are considered to be Class A IVDs.

  For example a wash solution for use on instrument XYZ. The wash solution is not specific to a particular analyte, however is specified for use on instrument XYZ.
- When a separately supplied reagent is intended for use in determining a specific analyte or parameter, or it is for use with a particular IVD, or it has a clearly defined purpose relating to its use with a group of similar or closely related tests, the reagent will be classified according to the class of the analyte or parameter it is intended to be used with.

  For example, a diluent or lyse solution intended for use when performing a full blood count (FBC) will be classified according to the class of the FBC assay, that is, a Class B IVD; a kit or individually supplied reagents intended to be used for the *in-situ* hybridisation of targeted gene polymorphisms, are classified under rule 3 as Class CIVDs for human genetic testing.
- A non-assay specific bacterial or viral RNA nucleic acid extraction kit intended for the extraction of pathogenic nucleic acid from a clinical specimen is a Class B IVD; a kit with a similar intended purpose of non-assay specific bacterial or viral RNA extraction, but which is dedicated for use on a specific instrument would be a Class A IVD.

4.3.7 Classification Rule 7 - Other IVDs are Class B IVD medical devices

An IVD medical device not mentioned in rules 1 to 7 is classified as a Class B IVD medical device

Rationale

Devices captured by this rule present a moderate individual risk or a low public health risk.

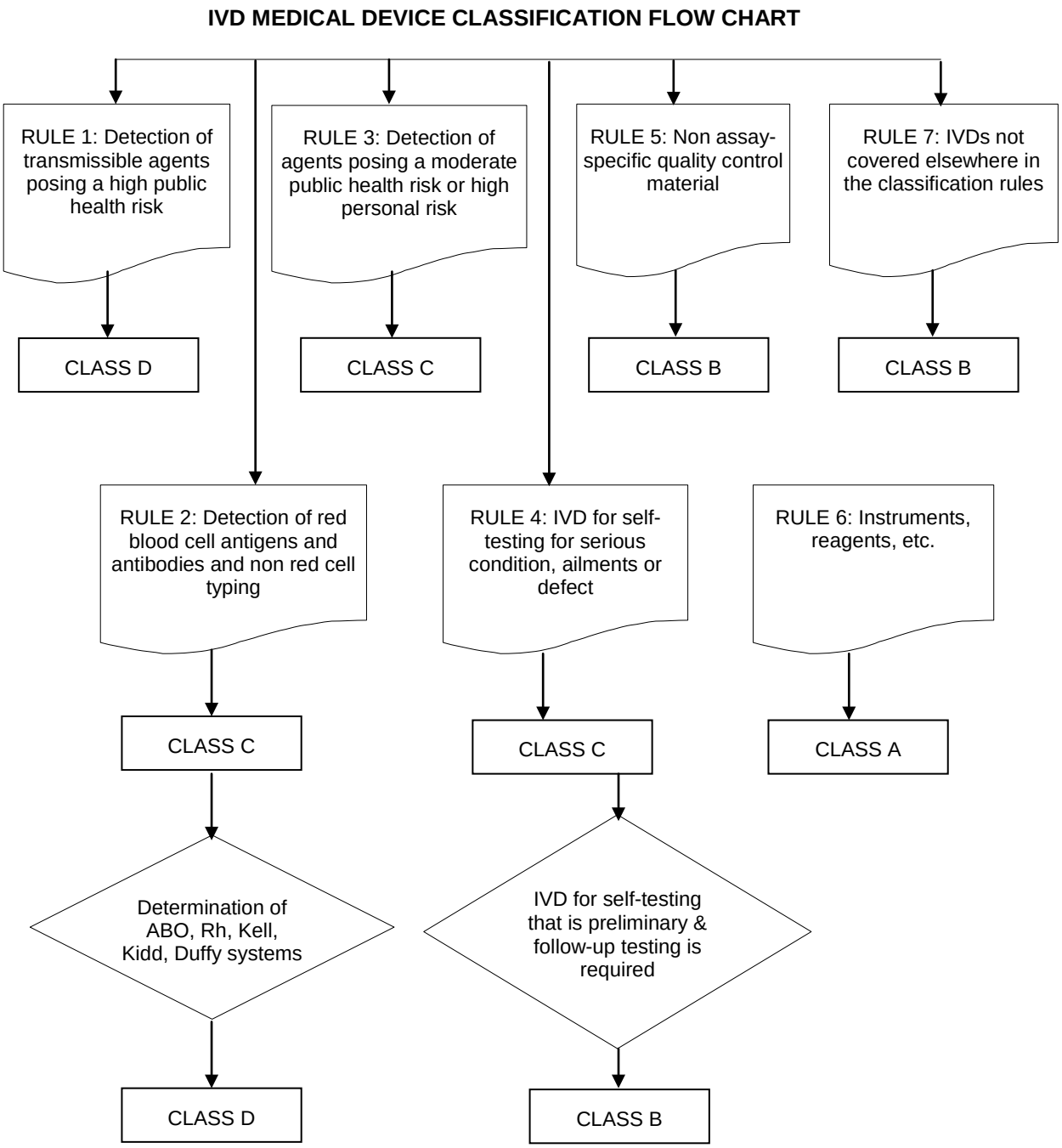
An erroneous result is unlikely to have a significant negative impact on patient outcome. The devices captured by this rule rarely provide the sole determinant for the correct diagnosis. If it is the sole determinant other information is available such as presenting signs and symptoms or clinical information, which may guide the physician.

This class also includes IVDs that detect infectious agents that are not easily propagated in a population.

Examples

- Most biochemistry tests for blood gases, hormones, vitamins, enzymes, metabolic markers and substrates are Class B IVDs.
- IVDs for performing coagulation testing are generally regarded as Class B IVDs, including activated partial thromboplastin time (APTT), factor assays and prothrombin time testing (other than prothrombin time for self-testing, which is captured as a Class C IVD by rule 4).
- Biochemical tests for establishing the presumptive identification of microbiological culture isolates, or for determining antimicrobial susceptibility of microbiological culture isolates, are Class B IVDs; however, confirmatory identification or serotyping reagents for microbiological culture isolates are classified according to the analyte being detected, e.g. Salmonella poly-O antisera or Haemophilus influenza serotype b typing reagent are Class C IVDs
- Cell culture lines for the culture of viruses present in clinical specimens are Class B IVDs.
- Tests to detect infection by *Helicobacter pylori*, *Clostridium difficile*, Adenovirus, Rotavirus and *Giardia lamblia* are Class B IVDs.
- Pregnancy tests for self-testing are Class B IVDs.

4.3.8 IVD Classification Flow Chart



5 FEES FOR MEDICAL DEVICES and IVDs

5.1 OVERVIEW

In accordance with the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) certain fees are payable to the Registrar of Medicines.

Each year, the level of fees and charges for medical devices will be reviewed in consultation with the Minister of Finance and will be published for comment prior to implementation.

Annual charges are payable each financial year for medical devices that are on the South African Medical Device Register and IVD Register, for any part of the financial year. The Medical Device Register and the IVD Register are the Council's record of the devices that are able to be supplied. The fees are published in the Government Gazette and are also available on the website.

Methods of payment: By cheque or electronic payment / direct transfer.

Also refer to the Bank Detail guideline for electronic payment / direct transfer.

Cheques should be made out to "Medicines Control Council". Only bank guaranteed cheques will be accepted and are to be submitted in a separate envelope attached to a copy of the covering letter of the relevant submission(s).

Direct electronic payment should include a clear reference, e.g. the product application number or purpose of the payment. Proof of electronic payment / direct transfer must be submitted in a separate envelope attached to a copy of the covering letter of the relevant submission(s).

To ensure evaluation of the relevant submission(s) (2.9.3 to 2.9.7 above) a copy of proof of payment/ cheque must also be attached to the original covering letter of the relevant submission.

Fees are charged for applications, assessments, and audits for new medical devices. Fees are also payable when there are changes that the Council needs to assess.

5.2 ANNUAL FEES

An annual fee is payable for

- maintaining a licence to manufacture, import or export or to import, distribute or export, or to wholesale a medical device or IVD and
- maintaining a medical device in the Medical Device Register and an IVD in the IVD Register.

The annual fees vary depending on the classification of the device. Different rates may apply for a:

- Class D medical device
- Class C medical device
- Class B medical device
- Class A medical device—supplied sterile
- Class A medical device—incorporating a measuring function
- Class A medical device

5.2 Annual Fees - continued

A new licence issued and a new medical device approved at any time during a financial year will be liable for the full annual charge for that financial year, in addition to the application and/or assessment fees paid. There is no reduction in the annual fee if a medical device is only on the South African Register for part of a year.

The invoices will include a complete list of Medical Device and IVD entries for each Applicant. Any discrepancies or omissions from the list of product entries should be notified to the Council immediately. Importers / Exporters/ Manufacturers also have an opportunity to review the devices listed in the invoice and identify any products that should be cancelled (where supply ceased before 1 July of that year).

Non-payment of annual fees for medical devices and or IVDs or maintenance of the licence for Manufacturers / Importers/ Exporters / Distributors / Wholesalers will result in the cancellation of the relevant products from the register/s or withdrawal of the licence as applicable. Once cancelled, a new approved application is required before supply of the medical device or activity of the Manufacturer/ Importer/ Exporter / Distributor / Wholesaler can resume.

5.3 FEES

The Council approved Conformity Assessment Bodies have a variety of fees for medical devices. They include:

- application fees
- conformity assessment fees
- application audit fees

5.3.1 Application fees

To avoid delays, importers, distributors and manufacturers should pay the application fee at the time of submitting an application. The application will not proceed until the fee is paid.

The following non-returnable fees are payable to the Council depending on the type of application.

The Council charges application fees to *inter alia*:

- apply for a change to, or recertification or update of a Conformity Assessment Certificate
- include a medical device in the SA Medical Device or IVD Register
- vary the Medical Device or IVD Register entry if the entry is incomplete, incorrect or requires an amendment due to technical changes
- obtain a Certificate of Free Sale or an Export Certificate, which are required by some countries that devices are exported to
- conduct a clinical investigation of a medical device in humans or animals
- A non-refundable screening fee payable with the screening submission.
- An application fee payable with the full submission of the application for registration.
- A registration fee, payable when the application complies with all the requirements for registration, and which is payable before a registration certificate is issued.
- A fee to cover any amendments to the dossier or certificate.
- A fee to cover any inspection of any manufacturing / distribution / wholesale / clinical site.
- A fee to cover authorization of the use of an unregistered medical device or IVD.

6 INCLUDING MEDICAL DEVICES IN THE SA MEDICAL DEVICE OR IVD REGISTER

6.1 OVERVIEW

The SA Medical Device Register and IVD Register is a register of medical devices accepted for importation into, supply for use in, or exportation from South Africa. The medical device registers can be viewed on the Council website www.mccza.com

Medical devices cannot generally be imported, supplied in, or exported from South Africa unless they are included in the Medical Device Register or IVD Register.

Only a South African Applicant can apply to include a medical device in the South African Medical Device Register or IVD Register

An Applicant can apply to include a medical device in the SA Medical Device Register or IVD Register if:

- the device complies with the Essential Principles
- appropriate conformity assessment procedures have been applied to the device

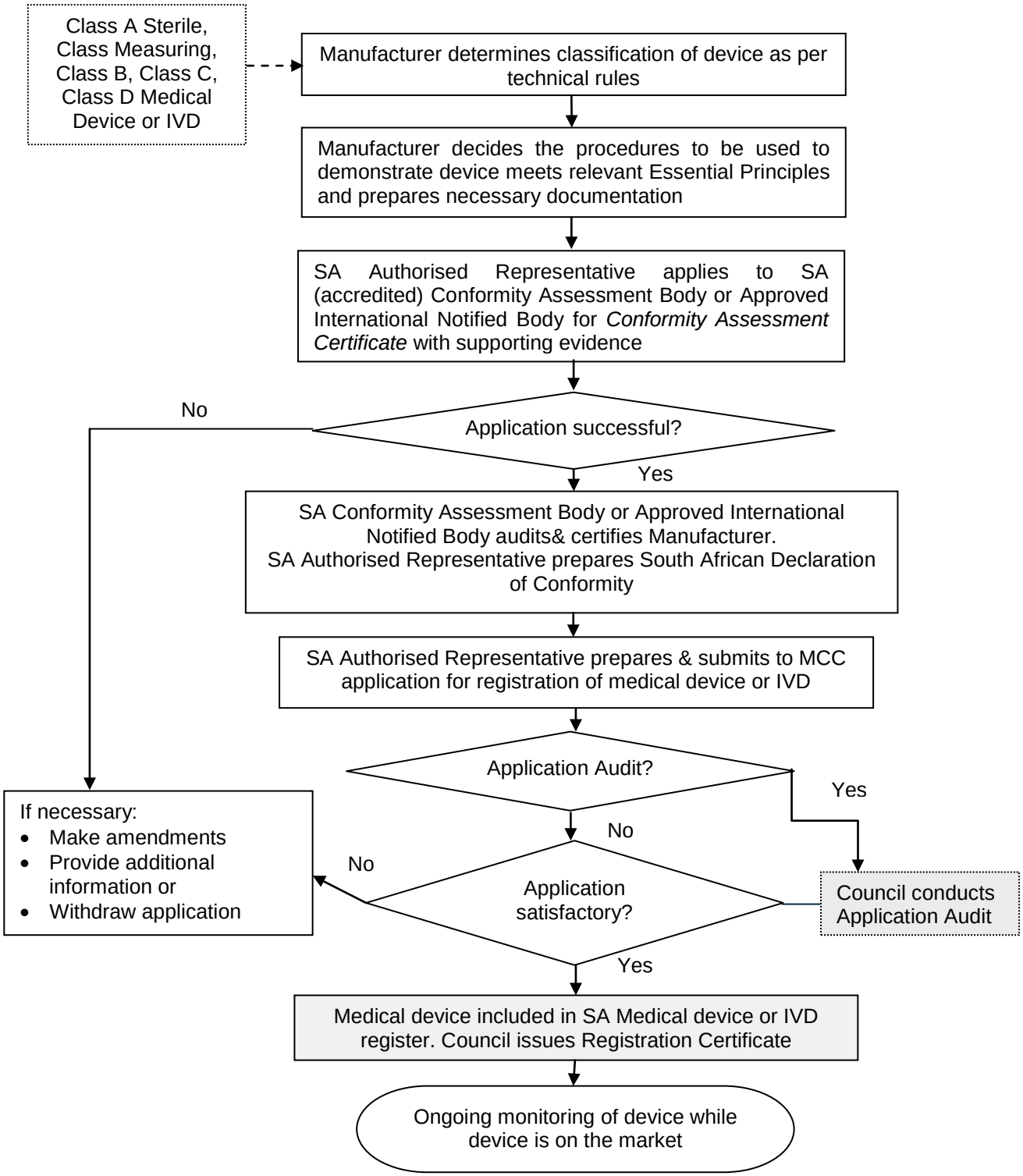
There are two slightly different processes for including medical devices in the SA Medical Device Register. There are processes for:

- Class A medical devices
- Medical devices other than Class A.

6.2 PROCESS FOR INCLUDING CLASS A DEVICES IN THE MEDICAL DEVICE REGISTER OR IVD REGISTER

The following flowchart summarises the process for including Class A medical devices in the SA Medical Device Register or IVD Register. For Class A measuring and Class A devices that are supplied sterile Applicants should refer to Medical devices other than Class A for supply in South Africa.

6.3 PROCESS FOR INCLUDING MEDICAL DEVICES OTHER THAN CLASS A IN THE MEDICAL DEVICE REGISTER OR IVD REGISTER



6.4 APPLICATIONS FOR INCLUSION IN THE MEDICAL DEVICE REGISTER OR IVD REGISTER

Any Applicant intending to sell a Medical Device or IVD in South Africa must lodge an application to include the devices in the Medical Device Register or IVD Register using the following process.

For a Class A device, Manufacturers must apply a conformity assessment procedure and prepare a Declaration of Conformity, with supporting documents. Applicants submit application for registration to the Council for inclusion. Council may include the device on the Register following appropriate assessment. Council maintains the prerogatives to request any additional information or evidence.

Manufacturer's Evidence is required for all other classifications of medical device. Applicants must submit the conformity assessment evidence with the application for registration to the Council as required.

In order to lodge an application, the Applicant must in accordance with the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and the General Regulations applicable to Medical Devices:

- complete the appropriate application form
- submit the completed application to the Council
- pay the prescribed application fee
- ensure that if conformity assessment evidence is required for the device that appropriate evidence has been obtained and is available
- certify that:
  - the devices are medical devices
  - the devices are intended for a specified purpose
  - the devices are correctly classified according to the South African medical device classifications
  - the devices comply with the Essential Principles
- an appropriate conformity assessment procedure has been applied to the devices
- have available sufficient information to substantiate the application of those conformity assessment procedures,
- the information included in or with the application is complete and correct

Successful Class A (non-measuring, non-sterile) applications, lodged with a current licence to manufacture, import or export, may result in inclusion in the Medical Device Register or IVD Register without any assessment.

All other applications may be selected for an application audit, which involves checking certain or all aspects of the application and certifications.

6.5 APPLICATION AUDIT

Prior to the inclusion of certain high risk medical devices in the Medical Device Register or IVD Register the Council will conduct an application audit, however where the conformity assessment evidence is a current South African Conformity Assessment Certificate an application audit may not be required, as per the Council's discretion.

6.5 Application Audit - continued

The following devices will be selected for an application audit:

- a medical device that is intended by the manufacturer to be used for disinfecting another medical device
- a Class D medical device
- Active medical devices which are Class C medical devices and Class D medical devices
- Class D procedure packs using a declaration of conformity

However, if the conformity assessment evidence is for Class D devices - and a certificate of conformity issued under any mutual recognition agreement between Council and the third party that Council aligns itself with, an audit may not be conducted as per the Council's discretion.

Applicants to note that if an application to include a device in the SA Medical Device Register or IVD Register is successful, the Applicant will be issued with a Certificate of Registration. In the event that the application is unsuccessful the Applicant will be informed accordingly.

6.5 TYPES OF MEDICAL DEVICES

An inclusion in the SA Medical Device Register or IVD Register is for a type of medical device. This means that an entry in the SA Medical Device Register or IVD Register may cover a family of products that are of the same type rather than individual devices. "Family"means a medical device comprising of the same type of device available in different models and sizes;

A medical device is taken to be of the same type as another medical device if they:

- have the same Applicant; and
- have the same manufacturer; and
- have the same device nomenclature system code; and
- have the same medical device classification; and
- are the same in relation to such other characteristics, either generally or in relation to medical devices of the type in question.

In relation to a Class D medical device (including Active medical device), a characteristic is the unique device identifier given to the device by its manufacturer to identify the device and any variants.

6.6 UNIQUE DEVICE IDENTIFIERS (UDIs)

As specified in the General Regulations to the Medicines and Related Substances Act, 1965 (Act 101 of 1965), the UDI is the combination of words, numbers, symbols, or letters assigned by the manufacturer to uniquely identify the device and any of its variants.

This is generally different to the catalogue or stock unit identifier assigned to the device.

Often, the family name, model names, and model/catalogue numbers will form a hierarchy in identifying the device.

Different manufacturers identify their product lines in different ways such as:

- using family names to identify a range of similar devices
- uniquely identifying each device with a model number
- a combination of both these approaches

6.7 GLOBAL MEDICAL DEVICE NOMENCLATURE (GMDN) CODES

GMDN are codes are used by regional or national regulatory bodies to consistently describe medical devices. GMDN codes are used to assist in the:

- consistent assessment of devices before they are approved for supply
- ongoing monitoring of devices once they are available for supply

The GMDN database is a collection of terms that use a unique 5-digit code to describe particular devices. *The database is maintained by a not-for-profit company based in the United Kingdom.*

International regulatory authorities, including the Council, liaise with the GMDN Agency to request amendments to existing codes and the creation of new codes. Other GMDN users may also make applications to the GMDN Agency. For more information please see the GMDN Agency website at <http://www.gmdnagency.org>.

When lodging an application to include a device with the Council on the Medical Device Register or IVD Register, the Applicant must specify the GMDN code that best describes the devices that they want to include in the Register.

6.7.1 Device nomenclature system codes

(1) In accordance with the Global Medical Device Nomenclature System Code, as set out in ISO 15225, the device nomenclature system code specified for a medical device is:

(a) Class D IVD medical device—the relevant preferred term; and

(b) Class D IVD medical device that is an immunohaematology reagent IVD medical device—the relevant Level 2 collective term; and

(c) Class C IVD medical device - the relevant Level 3 collective term, or if no Level 3 collective term exists, the relevant Level 2 collective term; and

(d) Class B IVD medical device - the relevant Level 2 collective term; and

(e) Class A IVD medical device - the relevant Level 1 collective term; and

(f) Class D medical device, Class C medical device, or a Class B medical device - the relevant preferred term; and

(g) any of the following—the relevant preferred term:

i. a Class A medical device that the manufacturer intends to be supplied in a sterile state;

ii. a Class A medical device that has a measuring function;

iii. a Class A medical device for which there is no relevant template term; and

(h) for any other Class A medical device—the relevant template term.

(2) ***collective term*** means a term that:

(a) is used for those medical devices that share common features; and

(b) is identified in the Global Medical Device Nomenclature System Code;

6.7.1 Device nomenclature system codes

Examples of the use of a collective term include the following:

(a) to illustrate the scope of certificates issued by conformity assessment bodies when assessing which groups, families or types of medical devices are covered within a manufacturer's quality system;

(b) to identify the range of skills and general technological abilities for which a conformity assessment body has been approved and is so appointed by the relevant regulatory authority;

(c) for the exchange of information between regulatory authorities when general information on individual manufacturers' capabilities is notified.

ISO 15225: means International Standard ISO 15225: (Nomenclature—Specification for a nomenclature system for medical devices for the purposes of regulatory data exchange).

relevant preferred term, for a medical device, means the preferred term for that device under ISO 15225:

relevant template term, for a medical device, means the template term for that device under ISO 15225:

Note: Where there is no clear GMDN term for a particular medical device, the GMDN term that most closely matches the product should be used by the Applicant for the purposes of including the medical device with the Council in the Medical Device Register or IVD Register. This may mean that the GDMN 'description' associated with the GMDN 'term' may not be strictly accurate. To enable Applicants and manufacturers to include medical devices in the Medical Device Register or IVD Register without the need to have new GMDN codes created, the Council focuses on ensuring that the GMDN term and intended purpose are consistent, rather than the GMDN description. The GMDN description does not appear on the Medical Device Register or IVD Register or the Medical Device Register or IVD certificate.

6.8 VARIANTS FOR CLASS D DEVICES (INCLUDING ACTIVEMEDICAL DEVICES)

Variant means a medical device the design of which has been varied to accommodate different patient anatomical requirements (for example, relating to the shape, size, length, diameter or gauge of the device), or any other variation approved by the Council for the purposes of this definition, provided that the variation does not change the intended purpose of the device.

The regulatory framework for medical devices recognises that many devices are provided in varying configurations, or with varying characteristics, such as size and length, while the intended purpose of each device is exactly the same i.e. a cardiovascular stent may be supplied in four different diameters and six different lengths. These variations are only to accommodate differing vessel diameters and occlusion lengths for different patients.

Therefore, Class C and Class D devices can have one or more variants associated with a single Medical Device Register or IVD Register entry. The current allowable variants are:

- Diameter (mm)
- Gauge (cm)
- Shape (of tip)
- Suture, no. of strands
- Volume (ml)
- thickness;

6.8 Variants for Class D Devices (including Active Medical Devices) - continued

- angle;
- offset;
- taper;
- number of holes;
- size; and
- height

Note: "size' may be described in terms such as '1 - 9' or 'A - F', rather than as 'cm' or 'mm';

Stabilisation, material and surface finishes are ***not*** *allowable variants;*

Primary and revision versions of an implant ***are different medical devices*** *- the 'shape' variant cannot be used as a means of grouping them into one reclassification application.*

7 INFORMATION ABOUT A MEDICAL DEVICE

7.1 OVERVIEW

Users of medical devices must be provided with information about the medical device. It should be noted that for many devices there may be more than one user, depending on circumstances.
For example, when used in the hospital setting a urinary catheter is used by a healthcare professional in the course of treating the patient, but when used at home for self-catheterisation the user may be the patient or the patient's carer.

In accordance with Regulation 23 and Regulation 24 and Regulation 25 as applicable, of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) all Medical Devices and IVDs must label a medical Device or IVD and must include an *Instructions for Use*. Applicants are requested to follow the format stipulated in the Regulations to the Act

Instructions for Use should be typed in double-spaced text and should be in at least the English language.

The printing quality of the *Instructions for Use* insert should be clear to enable duplication, for inclusion into various documents, during the evaluation and registration process. The spelling and grammar in the *Instructions for Use* text should be checked thoroughly before submission of the application.

In the case of a Medical Device or IVD that requires assessment by the Council prior to being listed in the Medical Device or IVD Register, Council may request references for each statement on the *Instructions for Use (IFU)* insert. In such case the reference(s) for each statement should be included in a broad margin on the right hand side of each page of the IFU for this purpose. The exact page/s should be stated. No references should however be included in the finalised printed *Instructions for Use*.

An electronic copy (Word document) on diskette or CD of the package insert should be included.

The information to be included on the label and the *Instructions for Use* can be summarised as follows:

Type of information	Description	Legislative reference
Label	Printed information supplied on or with the device or packaging. Where this is not practicable, other appropriate media may be used. Includes information: identifying the: device manufacturer explaining how to use the device safely	Regulation 23 of the Regulations Essential Principle 13.1, 13.2, 13.3
Applicant Details	The name of the holder of certificate of registrationand address provided with the device so that a user of the device can identify the holder of certificate of registration.	Regulation 23 of the Regulations
Instructions for Use	Information that must be provided with a device unless the device: • is Class A or Class B and • can be used safely for the manufacturer's intended purpose without instructions.	Regulation 24(for Medical Devices) and 25(for IVDs) of the Regulations Essential Principle 13.1, 13.2, 13.4

Note: Electronic media such as information on websites and CDs may also be used to provide information about medical devices. Where a manufacturer chooses to use a media in addition to the printed form, they must also be able to supply the information in printed form if requested by the user.

Providing the instructions for use through a website identified on the product labelling only, is not sufficient to comply with Essential Principle 13.

These forms of media must comply with the requirements for printed materials.

7.2 IMPLANTED DEVICES

The user of an implanted device may be considered to be both the:

- recipient of the device—the person who has the device implanted in his or her body
- the health professional that implants the device

Essential Principle 13.4 (19) requires information about any risks associated with implantation of an implantable medical device to be provided with the device. Therefore, it is recommended that the following information be provided for devices that are implanted:

Type of device	Information recommended	Examples
All implantable devices	Manufacturers should, wherever practical, provide information to the recipient about: • the materials the device is made from • the model and manufacturer • if the device might trigger security screening machines (for example at airports) • whether there will be safety issues if a MRI machine is used on the recipient	• bone plates • bone screws • staples • tissue adhesives • sutures

Type of device	Information recommended	Examples
	Note: because of the simple nature of devices such as sutures, staples and tissue adhesive, and the way in that they are dispensed and used, it may not be necessary to provide any form of detailed information to the recipient or patient.	
Devices with an electronic or mechanical action	In addition to the recommendations for all implantable devices outlined above, manufacturers should provide device registrations cards or similar documentation to the recipient, providing information about the implant, the manufacturer and the name of the Holder of Registration Certificate.	• Active implantable medical devices • major orthopaedic implants • heart valves
Devices that contain a medicine	In addition to the recommendations for all implantable devices outlined above, manufacturers should provide details of the medicine, in case of: • hazard alerts • adverse drug interactions between drugs in/on the device and other medicines the recipient may be taking or need to take • Any contra-indications, warnings, restrictions, or precautions that may apply in relation to use of the device	• drug-eluting stents and leads

In accordance with Essential Principle 2(2) the manufacturers and the prospective holder of the registration certificate should undertake a documented benefit/risk assessment where there is a question about the practicalities of supplying the required information to the patient. This assessment should take into account the requirement of Essential Principle 13.1(1) to have regard to the training and knowledge of potential users of the device when preparing the information to be provided with a device. This assessment must be available for review by the Council if requested.

7.3 INSTRUCTIONS FOR USE

Regulations 24 and 25for Medical Devices and IVDs and Essential Principle 13.4 of the Regulations detail the South African requirements for *Instructions for Use*. The Essential Principle is provided below.

Instructions for Use are not required or may be abbreviated if the device is Class A or Class B and can be used safely for the manufacturer's intended purpose without instructions

Instructions for Use may be provided on the device itself; however, it is generally not practical to include all the required information because of size constraints.

The *Instructions for Use* are required to be provided if the device is supplied individually on the packaging for the device, when multiple devices are packaged together, on the packaging for the devices or separately with the device in printed form or may be in addition supplied electronically.

The *Instructions for Use* of a medical device need not be provided with the device, or may be abbreviated, if

- the device is a Class A medical device, a Class B medical device or a Class A IVD medical device; and
- the device can be used safely for its intended purpose without instructions.

The *Instructions for Use* of a medical device must include information mentioned in the Regulations to the Act as per General Regulation 24 for Medical devices and Regulation 25 for IVDs.

7.4 ADVERTISING

The Medicines and Related substances Act, 1965 (Act 101 of 1965) defines an advertisement as

***'advertisement'**, in relation to any medicine or Scheduled substance or medical device, means any written, pictorial, visual or other descriptive matter or verbal statement or reference-*

(a) appearing in any newspaper, magazine, pamphlet or other publication; or

(b) distributed to members of the public; or

(c) brought to the notice of members of the public in any manner whatsoever,

which is intended to promote the sale of that medicine or Scheduled substance; and 'advertise' has a corresponding meaning".

Advertisement therefore includes any information including:

- product labels
- pamphlets
- Instructions for Use
- promotional samples
- promotional seminars, demonstrations and displays
- advertorials
- advertisements for health services or treatments that identify a medical device

All advertising of medical devices and IVDs must comply with requirements of Regulation 22the General Regulations applicable to Medical Devices.

8 ACTIVE MEDICAL DEVICES

8.1 OVERVIEW

An active medical device is a device that uses and converts energy in a significant way in order to operate. An active device may use any form of energy except for gravitational or direct human energies.

Active devices may run from internal or external power sources. Examples of active devices include:

- pacemakers (electrical energy)
- electric hospital beds (electrical energy)
- gas-powered suction pumps (pressure energy)
- software (electrical energy—software is a controlling agent for an electrical device)
- active warming blankets (electrical and thermal energies)
- X-ray machines (electrical and ionising electromagnetic radiation energies)
- surgical lasers (electrical and electromagnetic radiation energies)
- lung ventilators (electrical and pressure energies)
- ultrasound machines (electrical and acoustic energies)

Devices that are powered by gravity or directly by a human being are not active devices. Examples of these devices include:

- gravity fed intravenous infusion sets
- traction systems
- hand-operated bag/valve/mask respirators/resuscitators
- hand-powered drills

8 Active medical devices, Overview - continued

Some devices are intended by their manufacturer to transmit energy, a substance, or another element between an active medical device and a human being without any significant change occurring to the element being transmitted. These devices are not regarded active medical devices. Examples include:

- electroencephalograph (EEG) leads (purely passive reduction in electrical signal)
- tubing sets (reduction in transferred pressure along the tubing).

An active medical device:

(i) means a medical device that is intended by the manufacturer:
- to depend for its operation on a source of electrical energy or other source of energy (other than a source of energy generated directly by a human being or gravity); and
- to act by converting this energy; but

(ii) does not include a medical device that is intended by the manufacturer to transmit energy, a substance, or any other element, between an active medical device and a human being without any significant change in the energy, substance or other element being transmitted.

Manufacturers of active medical devices must consider all classification rules and must meet all of the relevant Essential Principles.

The following Essential Principles and classification rules are specific to active medical devices:

The requirements are outlined in	which is located in the	and
Essential Principle 9.2 - Minimisation of risks associated with use of medical devices	Essential Principles	outlines requirements for the risk of reciprocal interference involving other devices
Essential Principle 12 -Medical devices connected to or equipped with an energy source	Essential Principles	outlines requirements for the safety and performance of active devices.
Rules 9 – 12: Special rules for active medical devices	Technical Rules for Classification of Medical Devices	provides information for determining the classification of an active device.
Rules5 – 8: Special rules relating to active implantable medical devices	Technical Rules for Classification of Medical Devices	provides information for determining the classification of active implantable medical devices and associated medical devices.

8.2 DIFFERENT FORMS OF ENERGY

The following table describes different forms of energy in order to help the reader determine if his or her device is active or not.

Form	Description	Comments	Medical Device Examples
Chemical energy	Stored in batteries, liquids, gases, fuel, etc.		Chemical hot/cold packs
Elastic energy	Energy is stored when something is stretched, squashed, etc.	Includes clockwork-powered devices, spring-powered devices, elastically-powered devices, etc. Although human power is often applied to these devices in order to elastically deform, compress, or stretch them, the energy of operation is a transformation of the stored potential energy into kinetic energy.	Spring-loaded syringe drivers Bellows drains
Electric energy	Electrical energy is used to drive the action of the device, for example, turn a motor, emit heat, emit light, or emit electrical signals.	Mains (230V grid) power and batteries are the primary sources of electrical energy, although there are other methods of generating electric energy.	Blood gas analysers (which measure electric potential relating to concentrations of gases in blood) Electric devices such as drills All electronic devices and computers Software (used to control a computer)
Radioactivity	Stored in the nuclei of atoms where energy is released from bonds in the nucleus rather than via the release of the electrons (see Electric energy above).	The decay of isotopes is used for medical imaging and for cancer treatments (radiation oncology).	Radioactive seeds/beads
Magnetic energy	Magnetic potential energy is closely related to electric potential energy (see above).A magnetic field can also impart energy to a particle within it.	Electric motors operate from magnetic fields interacting with electric currents in order to rotate. An alternator or electric generator works in the reverse: a (motor) generator is externally rotated, resulting in the generation of an electrical current.	Magnetic Resonance Imaging (MRI) machines use a magnetic field (and also radio waves) to excite particles within biological tissues Electric dentist drills

Form	Description	Comments	Medical Device Examples
Electromagnetic radiation	Electromagnetic radiation is a flow of electromagnetic energy waves ranging from very long-wavelength radio waves to microwave, infrared, visible, ultraviolet, and x-rays, through to very short wavelength gamma rays.	Electromagnetic radiation is microscopic kinetic (movement) energy.	UV phototherapy cabinets (for treating psoriasis); and X-ray imaging and therapy devices
Thermal energy	Thermal (or heat) energy is microscopic movement energy. It is often realised as infrared waves.	Hot water packs are not active devices as there is no change in the form of energy.	Electric warming blankets Respiratory humidifiers Chemical heat packs.
Pressure energy	Pressure is stored as potential energy and is often converted to kinetic (movement energy) via conversion of a high-pressure source to a low pressure one.	The conversion is then from an amount of potential energy to an amount of kinetic energy and a smaller remaining amount of potential energy.	Air turbine- powered dentist drill — a flow of released compressed air (potential pressure energy) pushes on the blades of the turbine (this is a conversion of potential to kinetic energy) and transfers some of this airflow into rotation of the turbine shaft
Sound/Acoustic/Sonic	Sound or acoustic energy is a form of kinetic energy, realised as sound/air-pressure waves.	Many of these devices derive their primary power from an electrical source.	Ultrasound imagers; Hearing aids; Ultrasonic nebulisers; Tinnitus maskers; and Lithotripters.

8.3 ELECTROMEDICAL SAFETY STANDARDS

Electromedical devices are powered by electricity—mains, battery and low-powered devices. Examples are pacemakers, pulse oximeters, and blood-pressure monitors.

There are potential safety risks to the patient and/or user if the medical device:

- causes the patient and/or user unintended exposure to electrical currents
- interferes with or affects another electromedical device—Electromagnetic Compatibility (EMC).

To ensure that manufacturers of electromedical devices have considered these risks they must demonstrate compliance with at least the following Essential Principles:

- Essential Principle 9.2 - Minimisation of risks associated with use of medical devices
- Essential Principle 12 - Medical devices connected to or equipped with an energy source.

The most common way to demonstrate compliance is to meet a standard published by a South African or international standards agency, or a similar standard. If the manufacturer chooses to use other voluntary standards they must provide evidence that the chosen standard is applicable to the manufacturer's device and that its application satisfies the requirements of the Regulations. The use of such standards is not mandatory.

Standards that are commonly used to demonstrate compliance include:

Standard	Description
IEC 60601: General requirements for basic safety and essential performance of medical equipment and any applicable sub-parts	Applies to the basic safety and essential performance of all general medical electrical equipment such as defibrillators, electrical beds, ECG machines
IEC 60601-1-2: Collateral standard for electromagnetic compatibility (EMC) of medical equipment	Specifies general requirements and tests for EMC of medical equipment. Collateral standards serve as the basis for specific standards by applying additional requirements to those prescribed in the associated general standard(s).
IEC 61010.1: General requirements for safety of electrical equipment for Measurement, Control, and Laboratory use (e.g. IVD equipment, sterilisers)	This international standard is applicable for some medical devices that are not in direct contact with patients. Examples include bench-top sterilisers and *ex vivo* tissue-processing equipment

8.3.1 Medical devices that connect to the public mains electricity supply

In South Africa, the public mains electricity supply is 220 - 250 volts, 50 Hz. The internationally accepted IEC 60884-1: Plugs and socket outlets for household and similar purposes – part 1: General rules - electrical equipment must be connected to a mains electricity supply using a plug with active and neutral pins partially insulated and with South African-specific pin configuration.

In addition a transparent plug cover should be used if the plugs are re-wireable. For moulded plugs, it is preferable that the plug cover is transparent but this requirement is not mandatory.

8.3.2 Electromagnetic Compatibility (EMC)

EMC and the influence of the expected environment should be considered when determining the risks associated with the use of a medical device. Environments include domestic, clinical, and critical-care areas. EMC requirements also apply to battery-powered devices.

The first step in determining compliance with EMC requirements is to perform a thorough risk analysis. Ideally, such an analysis should be undertaken as part of an overall risk management process as defined in ISO 14971. The risk analysis must form the basis for specifying EMC test requirements.

Manufacturers should consider the highest potential-risk environment to determine the amount and type of testing required. The standards provide guidance for the type and amount of testing required. Manufacturers may also need to consider specialised aspects not covered by a standard. It is generally expected that EMC testing be conducted by an accredited test laboratory due to the highly specialised nature of the testing.

The manufacturer should include testing for:

- protection of the public mains network—IEC 60601-1-2. Main network testing is not applicable to battery-powered devices unless a battery charger forms part of the device
- emissions—IEC 60601-1-2
- immunity—IEC 60601-1-2

Life-supporting equipment used in a clinical environment normally require full compliance with the IEC 60601-1-2 standard, including more stringent EMC requirements imposed by an IEC 60601 part 2 standard, since higher levels of immunity are necessary in order to establish a broader safety margin. For example, the part 2 standard, IEC 60601-2-31, imposes additional EMC requirements for external pacemakers.

Less stringent requirements normally apply to non-life-supporting equipment used in a clinical environment (e.g. suction pump). IEC 60601-1-2 makes allowance for waiving immunity testing, provided the manufacturer can justify essential performance via the risk analysis. As per Essential Principle 13.4, the *Instructions for Use* for the device must also provide information to allow the user to manage the electromagnetic environment in the clinical setting.

Low-risk devices used exclusively in a non-clinical setting, such as a massager for domestic use, and that are clearly labelled as ‘not for use in a clinical setting’ or ‘for domestic use only’ may not require full compliance with IEC 60601-1-2. EMC compliance may be demonstrated by justifying essential performance via the risk analysis as indicated in IEC 60601-1-2. If such an analysis demonstrates that the device does not pose any inherent hazards, either alone or in connection with other equipment, then the following minimum EMC requirements may apply:

- Labelling or *Instructions for Use* that indicate that the device was not tested to clinical EMC requirements

8.3.3 Telecommunications and Radio-Communications Transmitters

The Independent Communications Authority of South Africa (ICASA) is the regulator for the South African communications, broadcasting and postal services sector. ICASA was established by an Act of statute, the independent communications Authority of South Africa of 2000, as Amended. ICASA's mandate is spelled out in the Electronic Communications Act for the licensing and regulation of electronic communications and broadcasting services.

The ICASA administers regulatory systems relating to a device's compliance with:

- South African telecommunications
- Electromagnetic compatibility requirements and radio-communications standards.

Medical devices with telecommunications ports must comply with the relevant guidelines and legislative requirements for these types of devices

8.3.4 Radioactive medical devices

All medical devices that are radioactive are active medical devices. If radioactive medical devices are implantable (AIMDs) they are classified as Class D.

Radioactive medical devices are radioactive products that do not have a pharmacological, immunicological, or metabolic action, or that are administered locally rather than systemically, for example brachytherapy spheres are active implantable medical devices. Their primary mode of action is radiation, and the basis for the therapeutic claims for the product is that the radiation affects the tissue irradiated. The mechanism of such action on the tissue is physical in nature. The only way that such an action can take place is via an energy conversion at the tissue interface - the precise nature of the energy conversion may vary from temperature effects to denaturing of cellular molecules, or other physical interaction that leads to tumour cell death.

In vivo imaging agents (such as barium meals) are regulated in South Africa as medicines.

The MCC together with the National Nuclear Regulator regulates the supply of radioactive medical devices in South Africa.

The South African National Nuclear Regulator (NNR) is primarily mandated to monitor and enforce regulatory safety standards for the achievement of safe operating conditions, prevention of nuclear accidents or mitigation of nuclear accident consequences, resulting in the protection of workers, public, property and the environment against the potential harmful effects of ionizing radiation or radioactive material. The NNR is directly accountable to parliament through the Minister of Energy on nuclear and radiation safety issues. More information is available on the NNR website at <http://www.nnr.co.za>.

8.3.5 Radiating medical devices

The manufacturers of radiating medical devices must comply with Essential Principle 11.

Examples of radiating medical devices include:

- medical lasers
- phototherapy devices
- X-ray machines
- dental curing lamps

8.3.5 Radiating medical devices - continued

- Radiating beauty therapy products such as:
  - solariums
  - laser combs
  - dermal abrasion devices (or dermal abrasion products that apply energy to the patient)
  - skin rejuvenation devices (or skin rejuvenation products that apply energy to the patient)

Hair removal products that apply energy to the patient are not medical devices unless:

- therapeutic claims are made or
- the product is
  - surgically invasive, or
  - invasive via a body orifice.

8.3.6 Software

Software operates as a controlling agent for an electronic device, e.g. a microcontroller or computer.

Software is regulated in different ways depending on the manufacturer's intended purpose for the software and how it is supplied:

Type of software	How is it regulated?	Examples
Software that is part of a device and is supplied with a medical device	Part of the device	• Pacemaker firmware • Embedded patient monitor software
Software or an accessory to a device that is a device in its own right if it is supplied separately from the related device	A separate medical device	• Image-processing software for use with an X-ray machine • Pacemaker programmer and controller for use on a personal computer or laptop
Software that is used as a diagnostic or therapeutic tool	A separate medical device	• Oncology image-processing tool • Radiation planning/treatment Software
Upgrades to software supplied separately	A separate medical device	• Upgrade to image-processing software to add artificial colouring of images • Upgrade to ultrasound equipment to allow 4-dimensional images
Corrections to software errors that have been supplied with a device *Please note:* must be a replacement part with no additional functionality.	Not a medical device	• Bug fix to stop infusion pump indicating incorrect drug administration values • Stability fix to image processing tool to reduce incidence of crashing or freezing
Software that is used in combination with other equipment for handling general patient-related information	Not a medical device	• Patient record management system (admission dates, case notes, contact details) • Conversion, compression, and encryption functionality/tool • Clinical Information System (CIS) without diagnostic or therapeutic functionality

8.3.6 Software - continued

The regulatory requirements apply to all forms of medical device software including software that is embedded (for example, firmware in hardware) such as:

- field-programmable gate arrays (FPGAs)
- electronic programmable read only memory (EPROM)
- flash memory
- static or dynamic random access memory (RAM)

Software often forms an integral part of an electronic device, for example, in a pacemaker or patient monitor. In these cases, the software is a part of the device and is not considered to be a separate or distinct device.

Software that fits the definition of a medical device in its own right requires separate entry on the South African Medical Device Register, which means that the prospective holder of the registration certificate must lodge an application with the Council to include the device in the Medical Device Register.

Some devices have more than one type of software residing within them. For example, an infusion pump monitor system may have software:

- to control the infusion parameters—Class C
- for the logging of patient data—Class A

If the device is supplied as a complete unit, the classification of the complete device is the highest classification—Class C. If the software is supplied separately, the individual classification of each device applies.

The international standard *IEC 62304 Medical device software—Software life cycle processes* addresses requirements that are specific to software, while the *IEC 62366 Medical devices—Application of usability engineering to medical devices* standard addresses usability engineering requirements to all devices, including those that are wholly or partially software-based. The Council considers these standards as representing the state-of-the-art for medical device software.

The labelling requirements apply to medical device software, regardless of whether it is downloaded from the Internet, installed from a CD, pre-installed on a device

Manufacturers need to ensure that the product information, such as the graphical user interface, screenshots, CD labels, and product demos meet the requirements of Essential Principle 13.

9 MEDICAL DEVICES INCORPORATING A MEDICINE

9.1 OVERVIEW

There are products that have both a medicine and a medical device component and it is the combination of the two components that deliver the desired therapeutic effect. In deciding how these products are regulated, the Council considers:

- the primary intended purpose
- the mode of action of the product

as they relate to the definition of a medicine and a medical device.

9.1 Medical Devices incorporating a Medicine, Overview - continued

In deciding on the status of a product to be either a medical device or a medicine, the applicable definitions from the Act for a medicine and medical device need to be considered when determining whether a product that has both a medicine and a medical device component is to be regulated as a medicine or a medical device.

Normally a medical devices incorporating a medicine means a medical device of any kind that incorporates, or is intended to incorporate, as an integral part, a substance that:

(i) if used separately, would be a medicine; and

(ii) is liable to act on a patient's body with action ancillary to that of the device

Examples of devices that this guidance applies to include (but are not limited to):

- catheters coated with an anticoagulant or an antibiotic agent
- medicine-coated coronary artery stents (drug-eluting stents)
- bone cements containing antibiotics
- sponge impregnated with antibiotics
- intraocular viscous solution with anaesthetic
- medicated root canal sealant
- silver impregnated dressings
- Surgical adhesive of collagen (medical device) and thrombin (medicine) packaged as two components that are not applied to patient until mixed together and 'intended to incorporate an ancillary medicine'.

Groups, System or procedure packs that include at least one medical device and may contain a medicine are regulated as medical devices, however the medicine must be registered by the Council in its own right before an application for the system and procedure pack can be lodged.

If the decision for the product to be regulated as a medicine or a medical device is not obvious from consideration of the intended purpose and the mode of action, the matter should be referred to the Council for determination.

Essential Principle 7.4 requires that the safety and quality of the medicinal substance be verified in accordance with the requirements for medicines and that the ancillary action of the substance be verified having regard to the intended purpose of the device

Classification Rule 13 indicates that medical devices are Class D if they incorporate, or are intended to incorporate, as an integral part, a substance that:

- if used separately would be a medicine; and
- is liable to act on the patient's body with an action ancillary to that of the device.

Where an application for registration is made for a medical device incorporating a medicinal component, with relevant manufacturer's evidence to support the SA Declaration of Conformity, at the time of the application audit, the relevant parts of the Dossier are referred to the Council by the Registrar for evaluation of the medicinal component. The medicinal assessment is undertaken in parallel with the assessment of the medical device and the relevant fees for the assessment of the medicine component will also apply. The manufacturer should ensure that they have included data for the medicinal substance as part of the Dossier in submissions.

If a medicine is considered to be a new chemical entity (NCE) the medicine is also required to undergo the approval processes for a NCE; this includes forwarding data relating to the medicinal component of the device to the Registrar for the Council to consider the safety, quality and efficacy of the medicine as per the format outlined in the Common Technical Document (CTD) format, which is available on the Council website.

10 MEDICAL DEVICES CONTAINING MATERIALS OF ANIMAL, MICROBIAL OR RECOMBINANT ORIGIN

10.1 OVERVIEW

Some medical devices contain materials that are of non-viable animal, microbial, or recombinant origin.

Medical devices incorporating these materials pose a special risk for both patients and healthcare providers due to, for instance, the potential for pathogen transmission to humans.

There is particular concern with regard to the possible transmission of Transmissible Spongiform Encephalopathies (TSEs) associated with materials originating from some animal species.

If a medical device or the cell-culture media used for microbial cell-culture contain animal-derived material, the Council requires manufacturers to comply with the requirements outlined in the Council approach to minimising the risk of exposure to Transmissible Spongiform Encephalopathies (TSEs) through medicines and medical devices.

10.2 DESCRIPTIONS OF THE KINDS OF MATERIALS

Origin	Description	Examples
Animal	An invertebrate or vertebrate member of the animal kingdom	Bovine, porcine, lapine, etc Crustacean Coral
Microbial	Micro-organisms	Bacteria Yeast
Recombinant	Genetically modified (GMO) biological organisms	Microbial cells Animals Plants

Examples of medical devices containing these materials

Medical devices	Materials
Biological heart valves	Porcine valve, valves made of bovine or equine pericardium
Wound dressings	Gelatine or collagen from porcine skins; recombinant plant expressing human collagen genes
Collagen corneal shields	Collagen from porcine skins
Vascular grafts	Coated with porcine collagen or gelatin

Medical devices	Materials
Catgut sutures	Bovine or ovine animal intestines
Intra-ocular fluids Meniscus joint fluid replacement Anti-adhesion barriers Tissue augmentation Catheters with 'lubricious' coating	Hyaluronic acid extracted from rooster combs or harvested from a microbial cell line
Blood cell separation devices	Monoclonal antibody derived from microbial cell line expressing human gene

Requirements for medical devices containing these materials

Requirement	Reference	Description
Classification	Rule 14t	Medical device is Class D unless it: • only contains materials of animal origin that have been rendered non-viable AND • is intended by the manufacturer to only come into contact with intact skin
Conformity Assessment Certificate	Regulation 9.6	A Conformity Assessment Certificate must be issued and a South African Declaration of Conformity must be available before a valid application can be made to include the medical device in the Register of Medical Devices
Essential Principles	Essential Principle 8.2	Describes requirements for risk management, control measures including sourcing, selecting, harvesting, processing and validation methods for elimination/inactivation of viral or TSE agents.

All medical devices require classification to determine the relevant applicable conformity assessment procedures, and all medical devices are required to comply with all applicable Essential Principles. Some requirements apply specifically to medical devices containing materials of animal, microbial or recombinant origin.

The risk analysis that a manufacturer is required to perform to show compliance with the Essential Principles must take into account the presence or potential contamination by the materials of animal, microbial, or recombinant origin. A risk-management report for the medical devices containing materials of animal, microbial, or recombinant origin must be included in the Dossier for the medical device.

10.3 MEDICAL DEVICES INCLUDED IN CLASSIFICATION RULE 14

Medical devices containing non-viable animal tissues, cells or other substances, or microbial or recombinant tissues, cells or other substances.

Medical device captured by classification rule 14 requires a Conformity Assessment Certificate and a South African Declaration of Conformity by the Authorised Representative.

In the event that the Medical device contains:

- tissues, cells or substances of animal origin that have been rendered nonviable, or tissues, cells or substances of microbial or recombinant origin; or
- a combination of tissues, cells or substances of the kind described in paragraph (a)

the device is classified as Class D, unless:

- the device contains only tissues, cells or substances of animal origin that have been rendered nonviable; and
- the device is intended by the manufacturer to come into contact with intact skin only.

Note: The Council defines 'rendered nonviable' as referring to tissues and cells that have been processed to a point such that no further inherent capacity for cellular metabolic activity exists.

Also, products containing substances of microbial or recombinant origin are not captured in the EU by a special rule.

Classification Rule 14 includes medical devices

- in which the animal tissues, cells and their derivatives are used as:
  - raw and starting materials (i.e. example, collagen, hyaluronate, gelatin)
  - active substances (i.e. heparin)
  - excipients in the device (i.e. bovine serum albumin)
  - reagents used in production (i.e. porcine pepsin, albumin, meat broth etc. used in the culture of microbial cell lines)
- that contain tissues, cells or substances of:
  - microbial origin (production processes for example, biofermentation, harvested from microbial cell-culture; or in the finished product itself)
  - recombinant origin (for example, from any category of genetically modified organism and may be either during manufacture or in the finished product)

10.4 MEDICAL DEVICES CONTAINING MATERIALS OF ANIMAL ORIGIN NOT CLASSIFIED UNDER CLASSIFICATION RULE 14

Classification Rule 14 does not apply to:

- the following tissue or cellular derivatives:
  - bovine milk
  - silk
  - beeswax
  - hair
  - lanolin

10.4 Medical devices containing materials of animal origin not classified under Classification Rule 14 - continued

- sintered hydroxyapatite (process must be validated to demonstrate no evidence of organic material)
- tallow or tallow derivatives
- alcohols
- simple sugars or salts fermented from cultures that do not have any animal reagents
- microbial sourced enzyme cleaners

- a medical device that contains tissues, cells, or substances of animal origin that have been rendered non-viable where the device is intended by the manufacturer to come into contact with intact skin only (i.e. leather straps associated with limb prostheses).

(Honey is not considered to be an animal-derived substance.)

10.5 SELF ASSESSMENT FOR ANIMAL COMPONENTS WHERE THE DEVICE IS NOT CLASSIFIED UNDER CLASSIFICATION RULE 14 AND CONFORMITY ASSESSMENT BY COUNCIL IS NOT REQUIRED

In the event that the a device contains materials of animal origin and the device is not considered class D by Classification Rule 14,the manufacturer is required to comply with the international requirements and conduct a self-assessment for Transmissible Spongiform Encephalopathies (TSE) risk.

Self-assessment is described in more detail in the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMEA/410/01 Rev 2, October 2003).

Records are required to be kept and maintained by the manufacturer for those animal origin components.

Manufacturers of medical devices containing ingredients identified as having animal origin must comply with the requirements for each of the animal-derived ingredients, in accordance with Essential Principle 8.2.

Appropriate control measures must be implemented regarding animal material sourcing, selection, harvesting, and processing.

10.6 CONFORMITY ASSESSMENT PROCEDURES FOR MEDICAL DEVICES THAT CONTAIN MATERIALS OF ANIMAL, MICROBIAL OR RECOMBINANT ORIGIN

Manufacturers of medical devices containing:

- tissues of animal origin that have been rendered non-viable, or
- tissues, cells, or substances of microbial or recombinant origin,

are required to obtain a Conformity Assessment Certificate and a South African Declaration of Conformity by the Authorised Representative prior to applying to include the medical device in the SA Medical Device Register.

Essential Principle 8.2, part of Essential Principle 8 - Infection and microbial contamination, is particular to medical devices that contain materials of animal, microbial, or recombinant origin.

10.6 Conformity assessment procedures for medical devices that contain materials of animal, microbial or recombinant origin - continued

Essential principle 8.2 Control of animal, microbial or recombinant tissues, tissue derivatives, cells and other substances applies in relation to a medical device that contains:

- tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable; and
- tissues, tissue derivatives, cells or substances of microbial or recombinant origin.

(i) If the tissues, tissue derivatives, cells or substances originated from animals, the animals must have been subjected to appropriate veterinary controls and supervision, having regard to the intended use of the tissues, cells or substances.

(ii) If the medical device contains tissues, tissue derivatives, cells or substances of animal origin, a record must be kept of the country of origin of each animal from which the tissues, tissue derivatives, cells or substances originated.

(iii) The processing, preservation, testing and handling of tissues, tissue derivatives, cells or substances of animal, microbial or recombinant origin must be carried out in a way that ensures the highest standards of safety for a patient, the user of the device, and any other person.

(iv) In particular, the production process must implement validated methods of elimination, or inactivation, in relation to viruses and other transmissible agents.

When a manufacturer conducts a risk analysis during the design process for a medical device, the presence or possible presence of animal origin material in the finished medical device must be taken into consideration. This analysis must be undertaken, regardless of whether Classification Rule 14 is applicable to the medical device or not.

For medical devices constructed of recombinant or microbial origin material, or animal origin material that has been rendered non-viable, this analysis along with details of risk mitigation steps undertaken, must be provided when a dossier is submitted to the Notified Body in support of an application for a SA Conformity Assessment Certificate.

For medical devices not requiring a SA Conformity Assessment Certificate, this analysis along with details of risk mitigation steps undertaken, must be maintained in the Technical File held by the manufacturer, and be made available to the Council on request. Changes to the Technical File, in this case, do not require notification to the Council unless this is specifically requested.

Incidental contact with various substances of animal, microbial, or recombinant sources material during manufacture must be considered when deciding whether a SA Conformity Assessment Certificate is required.

Note that lubricants and cleaning agents of animal or microbial sources used solely during manufacturing and that do not end up in the finished medical device are not considered in the decision of whether a Conformity Assessment Certificate is required.

The manufacturer must apply to the Conformity Assessment Body or approved Notified Body for assessment prior to implementing a change to the design materials or manufacturing processes for medical devices for which the Conformity Assessment Body or approved Notified Body has issued a Conformity Assessment Certificate. Changes to the supplier of animal material are notifiable and assessable changes.

10.6 Conformity assessment procedures for medical devices that contain materials of animal, microbial or recombinant origin - continued

The manufacturer needs to undertake a risk analysis to determine whether changes to sourcing, collection or handling have reduced the safety of the product. The manufacturer also needs to consider whether this change affects the validation of the inactivation or elimination of viruses or TSE agents.

After this risk analysis and conclusions has been documented, notify the Council for confirmation of whether the proposed change(s) require Council approval.

10.7 SPECIFIC REQUIREMENTS FOR ANIMAL-ORIGIN COMPONENTS

There are special requirements for:

- medical devices incorporating tissues, their derivatives, or other substances originating from animals
- materials of animal origin that are used or that come into contact with medical devices during production processes where the materials are not included in the final device.

The Council has adopted ISO 22442 as a conformity assessment standard. ISO 22442 applies to medical devices other than *in vitro* diagnostic medical devices manufactured utilizing materials of animal origin, which are non-viable or have been rendered non-viable. It specifies, in conjunction with ISO 14971, a procedure to identify the hazards and hazardous situations associated with such devices, to estimate and evaluate the resulting risks, to control these risks, and to monitor the effectiveness of that control. Furthermore, it outlines the decision process for the residual risk acceptability, taking into account the balance of residual risk, as defined in ISO 14971, and expected medical benefit as compared to available alternatives.
ISO 22442-1:2007 is intended to provide requirements and guidance on risk management related to the hazards typical of medical devices manufactured utilizing animal tissues or derivatives such as:

- contamination by bacteria, moulds or yeasts;
- contamination by viruses;
- contamination by agents causing Transmissible Spongiform Encephalopathies (TSE);
- material responsible for undesired pyrogenic, immunological or toxicological reactions.

Compliance with these standards is not mandatory. However if a manufacturer chooses to follow a different approach, its relevance and adequacy in achieving a satisfactory level of safety must be demonstrated.

These standards specify relevant quality assurance techniques for the analysis and management of risk in the manufacture of medical devices, such as sourcing, collecting, handling of animal materials and their derivatives, viral and transmissible agent elimination and/or inactivation.

Documented compliance with these standards can form the evidence to demonstrate compliance with elements of Essential Principle 8.2.

The quality systems implemented by manufacturers of medical devices containing materials of animal origin must also ensure that the following are in place:

- quality control processes and procedures to prevent contamination with potential infectious/transmissible agents including TSEs and disinfection/decontamination procedures in the event of contamination; this includes adequate evidence of segregation between animal species in abattoirs or tissue supplier facilities

10.7 Specific requirements for animal-origin components - continued

- a documented system for animal and tissue traceability
- procedures for the selection, review, and auditing of tissue suppliers
- records of audit reports for the supplier of animal tissue by the device manufacturer
- name and address for the supplier of any animal materials. The Council treats animal-tissue material suppliers as key suppliers and the details of these suppliers are entered or referenced on the Conformity Assessment Certificate.

10.8 SPECIFIC REQUIREMENTS FOR MICROBIAL ORIGIN COMPONENTS

For medical devices containing components of microbial origin, manufacturers are also required to provide the following additional information:

- microbial species
- identification
- cell bank qualification to demonstrate that it has been fully characterised and tested for the absence of viruses
- composition of fermentation or growth media,
- identification of all components
- origin of components: animal, microbial, or plant
- suppliers, specifications, and certificates of analysis of the components.

10.9 SPECIFIC REQUIREMENTS FOR RECOMBINANT ORIGIN COMPONENTS

For medical devices containing components of recombinant origin, manufacturers are also required to provide at least the following additional information:

- identification and source of nucleotide sequence coding
- source of expression construct or host animals
- composition of fermentation or growth media, including:
- identification of all components
- origin of components: animal, microbial, or plant
- suppliers, specifications, and certificates of analysis of the components

10.10 OPTIONS FOR CONFORMITY ASSESSMENT CERTIFICATION FOR MEDICAL DEVICES CONTAINING ANIMAL ORIGIN MATERIAL

A manufacturer must apply to a Conformity Assessment Body or approved Notified Body for conformity assessment certification for medical devices containing animal origin material.

However, if a medical device contains:

- tissues of animal origin that contact intact skin only
- refined derivatives of animal derived waxes
- sintered hydroxyapatite
- heparin that conforms to pharmacopoeial standards
- gelatin that conforms to pharmacopoeial standards

11 GROUP, SYSTEMS AND PROCEDURE PACKS

11.1 OVERVIEW

'Group, system or procedure pack or procedure kit' are terms used to identify products that are packaged together for a specific intended purpose. Such a package must include at least one medical device but it can also contain medicines, other non-medicinal components. A group of products packaged together that meets the definition of 'group, system or procedure pack or procedure kit' is considered to be a medical device for the purposes of the Act.

Group, System or procedure packs or procedure kits:

- A package and goods in the package are a system or procedure pack if:
  - (i) the package and the items are for use as a unit, either in combination as a system or in a medical or surgical procedure; and
  - (ii) the package contains at least one medical device; and
  - (iii) the package and the items do not constitute a composite pack.
- To avoid doubt, a group, system or procedure pack or procedure kit is a medical device.

The terms "group", "system" and "procedure pack" or "procedure kit" are used in order to accommodate different types of packages that contain medical devices. Additionally, some manufacturers might use the term 'procedure pack' for a particular collection or combination of products (i.e. a collection of medicinal components for an appendectomy surgical procedure) while other manufacturers might refer to the same collection as a system. Nevertheless, no regulatory distinction is made between these terms. The term 'component' is used to describe an individual item in a group, system or a procedure pack or kit.

A group, system or procedure pack or kit does not consist of an, individual item only, a collection of miscellaneous items that are not intended by the manufacturer to be used for a specific purpose or bulk packs of one or more items.

11.2 REGULATORY AND LEGISLATIVE REQUIREMENTS

The regulatory requirements for Groups, systems and procedure packs are the same as for other medical devices. Manufacturers of all medical devices must:

- ensure that their medical devices meet the Essential Principles
- apply appropriate conformity assessment procedures
- comply with the clinical evidence requirements
- undertake adequate post-market surveillance activities for all medical devices regardless of whether they manufacture a system or procedure pack or kit.

However, in addition, Manufacturers of Groups, systems and procedure packs and kits:

- must ensure that any applicable regulatory requirements are met for each individual component in the system or procedure pack or procedure kit
- must ensure that all components are mutually compatible with the intended purpose of the system or procedure pack or procedure kit and:
  - o the intended purpose of each device
  - o the approved indications for medicines and any other component

11.2 Regulatory and legislative requirements - continued

Manufacturers wishing to utilise the conformity assessment procedure already undertaken by the component manufacturers may be eligible to use the conformity assessment procedures and may not necessary be required to hold conformity assessment certification for the assembly of that system or procedure pack.

Groups, systems and procedure packs and kits are treated as medical devices in their own right and, unless they are exempt (for example, custom-made medical devices), must be included on the SA Medical Device Register separately from the individual items in the system or procedure pack.

If individual or replacement component items in a system or procedure pack or kit are supplied for use separately from the system or procedure pack or kit, they require separate entry on the SA Medical Device Register from the system or procedure pack or kit.

Groups, systems and procedure packs and kits that are supplied on loan (for example, instrumentation for orthopaedic implant surgery) are regulated as medical devices and require inclusion in the SA Medical Devices Register.

11.3 DIFFERENT TYPES OF PACKAGES

11.3.1 Systems

Systems are comprised of components, including at least one medical device, that are intended by the manufacturer to be used in combination as a unit. A manufacturer will often supply one or more components of a system in a number of sizes in order to accommodate differences in patient anatomy.
Some example systems include:

- orthopaedic drill system, incorporating
  - drill
  - drill bits
  - burs
  - cables
  - a foot pedal
- knee joint-replacement system, incorporating
  - a femoral component
  - an articulating surface
  - a stemmed tibial plate
  - wedges
  - pins
  - screws
- patient monitoring system, incorporating
  - a monitor
  - ECG leads
  - blood-pressure cuff with cable
  - an infusion pump with tubing set

11.3.2 Procedure packs or procedure kits

Procedure packs or kits are comprised of components that are packaged together, including at least one medical device, and intended by the manufacturer to be used in a medical, surgical, or diagnostic procedure. Examples include:

- appendectomy surgical procedure pack, incorporating:
  - clamps
  - drapes
  - sutures
  - needles
  - forceps
  - scalpels
  - gauze
  - swabs
  - kidney dishes
- first-aid-kit, incorporating:
  - bandages
  - antiseptic ointment
  - tweezers
  - pain-relief tablets
  - adhesive strips
  - cotton buds
  - swabs

11.4 PRODUCTS AND ARTICLES THAT ARE NOT MEDICAL DEVICES

An article that is intended to administer a medicine in such a way that the medicine and the article form a single integral product that is intended exclusively for use in the given combination and that is not reusable (may be multi-dose) is not considered to be a medical device.

Examples include:

- a tube of cream with a specifically designed applicator to attach to the tube to deliver the required amount of cream
- eye or nasal medication with dropper that is specifically designed to attach or be attached to the medicine container to deliver the measured eye or nasal drops
- a syringe pre-filled with a medicine

11.5 COMPOSITE PACKS

Composite packs only contain medicines and their containers. They are entered on to the SA Medicines Register as medicines. Composite packs are used for a single treatment or for a single course of treatment. The components must either be combined before administration or be administered in a particular sequence. Examples include:

- vials of medicines administered in a sequence
- a powdered medicine for injection supplied with a diluting agent housed in a vial

11.6 CUSTOM-MADEMEDICAL DEVICES

Some Groups, systems and procedure packs and kits fit the definition of 'custom-made medical devices'. Custom-made medical devices are exempt from inclusion in the SA Medical Devices Register.

A system or procedure pack that contains one or more custom-made medical devices and no other kinds of medicinal items is also a custom-made medical device, and therefore is exempt from inclusion on the SA Medical Devices Register. However, a system or procedure pack that contains one or more custom-made medical devices, as well as medicines, or non-custom-made medical devices, is not a custom-made medical device and must be included on the Medical Devices Register.

11.7 CLASSIFICATION OF GROUPS, SYSTEMS AND PROCEDURE PACKS

When classifying a system or procedure pack, the manufacturer should note that the medical device component with the highest classification determines the overall classification for the system or procedure pack or kit, for example, a procedure pack or kit containing a Class D device will also be classified as Class D.

Any accessories to a system or procedure pack are classified separately with a system or procedure pack intended to be used in combination with another medical device classified separately to that other medical device.

The component manufacturer's intended purpose and classification applies. By changing the component manufacturer's intended purpose or classification, the system or procedure pack manufacturer assumes responsibility for the revised intended purpose for the component device.

The software used to drive or control a system has the same classification as the system.

- Class A systems or procedure packs that are supplied sterile are included on the Medical Device Register as 'Class A (supplied sterile)'
- Class A systems or procedure packs that are not supplied sterile but that contain a component that is supplied sterile are included on the Medical Devices Register as 'Class A' (non-sterile)
- Class A systems or procedure packs that contain a device with a measuring function are included on the Medical Devices Register as 'Class A (with a measuring function)'
- Groups, systems and procedure packs and procedure kits are classified without considering any component medicines or other therapeutic items

11.8 CONFORMITY ASSESSMENT PROCEDURE OPTIONS

Manufacturers of medical devices demonstrate that their devices conform to the Essential Principles by applying conformity assessment procedures.

Manufacturers of systems or procedure packs have two options:

- obtaining conformity assessment evidence for the entire system or procedure pack as a single kind of medical device, or
- using the conformity assessment procedures for Groups, systems and procedure packs

11.8 Conformity assessment procedure options - continued

Some manufacturers assemble procedure packs or systems from devices and other medicinal items that are manufactured by other (component) manufacturers. These system or procedure pack manufacturers either need to:

- apply for and obtain conformity assessment evidence for the entire system or procedure pack from a Conformity Assessment Body, or
- keep adequate documentary evidence of conformity for each of the component devices and prepare a South African Declaration of Conformity

11.8.1 Special Conformity Assessment Procedure

A special conformity assessment procedure allows manufacturers to assemble systems or procedure packs without being considered to be the manufacturer of each of the component devices (the component manufacturer); however, system or procedure pack manufacturers must keep adequate documentary evidence for each of the component devices.

For example, if a manufacturer assembles a surgical procedure pack that incorporates gauze, needles, sutures, scalpels, forceps, and some clamps, each supplied by different component manufacturers, they may use the special conformity assessment procedure if they can obtain documentary evidence for each component device within the pack from each of the component manufacturers.

An application to include a system or procedure pack in the SA Medical Devices Register that uses the special conformity assessment procedure is based on a Declaration of Conformity and does not require a conformity assessment certificate to be held by the manufacturer of the system or procedure pack, unless the system or procedure pack is supplied sterile. In this case, the system or procedure pack manufacturer must obtain certification for the sterilisation processes.

11.8.2 Eligibility for the Special Conformity Assessment Procedure

The special conformity assessment procedures can be used for Groups, systems and procedure packs if the manufacturer can meet the requirements as noted below.

Item	Requirement
Medical device	The system or procedure pack manufacturer must have documentary evidence (outlined in the next table) to demonstrate that each of the medical device components have: • met the Essential Principles • had the relevant conformity assessment procedures applied to them
Medicine	Medicines in the systems or procedure pack must be registered with the Council, unless the medicine is exempt
All component devices, and medicines	All components must be mutually compatible with the intended purpose of the system or procedure pack and: • the intended purpose of each device • the approved indications for medicines
Declaration of Conformity	The system or procedure pack manufacturer must make a South African Declaration of Conformity for the system or procedure pack.

11.8.2 Eligibility for the Special Conformity Assessment Procedure - continued

If the criteria for the special conformity assessment procedures cannot be met, the system or procedure pack manufacturer must apply the general conformity assessment procedures.

The documentary evidence required is as noted below.

Documentary evidence for manufacturers using the special procedure

Item	Requirement
For each component device	the system or procedure pack manufacturer must hold at least one of the following: • a South African Declaration of Conformity a Conformity Assessment Certificate from the component manufacturer • a CE certificate from the component manufacturer AND written agreement with the component manufacturer to supply technical documentation to the Council on request • a SA Medical Device Registration certificate AND agreement with the holder of the registration certificate of each component to supply technical documentation to the Council on request
For each component medicine	The system or procedure pack manufacturer must hold a certified copy of the MCC Medicines registration certificate for that component, unless the medicine is exempt.
For each component including any non-medicinal items	The system or procedure pack manufacturer must hold evidence to demonstrate that the components work together to achieve the intended purpose and are compatible with the other components in the system or pack
For sterile systems or procedure packs	The system or procedure pack manufacturer must hold appropriate conformity assessment evidence for the sterilisation processes for the system or procedure pack as a whole. This does not apply to systems or procedure packs that are non-sterile but include sterile component devices
For every component for the lifetime of the device and at least 5 years after manufacture of the last device	The manufacturer must have access to technical documentation, including: • South African Declaration of Conformity • certification and technical documentation. The system or procedure pack manufacturer must either hold or be able to arrange for these to be provided to the Council on request.
For each separate kind of system or procedure pack	The system or procedure pack manufacturer must provide a list of the contents.

11.8.3 Choosing to use the special procedure

The following examples describe when a system or procedure pack manufacturer may choose to use one of the usual conformity assessment procedure routes or to use the special procedure for Groups, systems and procedure packs:

11.8.3.1 Packs where evidence is not held for any of the component devices

The South African manufacturer *Gumtree Medical Manufacturing (Pty) Ltd* assembles Class B first-aid-kits from components it manufactures itself. The first-aid-kit includes some sterile device components but the first-aid-kit itself (as a whole) is not supplied sterile.

The manufacturer does not hold the required documentary evidence for any of the component devices and consequently is not eligible for the special conformity assessment procedure for Groups, systems and procedure packs.

The manufacturer must apply for a SA Conformity Assessment Certificate to cover:

- each of the component devices inside the first-aid-kit and thereby become eligible for the special conformity assessment procedure. The manufacturer would need to submit a change application any time they wanted to introduce a new component not included within the scope of the certificate. The certificate could also be used to support inclusions in the SA Medical Device Register for the separate supply of the individual components of the first-aid-kit.

and/or

- the first-aid-kit as a whole. The manufacturer would need to submit a change application any time they wanted to introduce a new first-aid-kit not included within the scope of the certificate. The certificate could not be used to support inclusions in the SA Medical Device Register for the separate supply of the individual components of the first-aid-kit.

11.8.3.2 Packs where evidence is held for some of the component devices

Manufacturer *Dryandra Medical Manufacturing (Pty) Ltd* assembles and sterilises surgical tubing procedure packs and wants to apply the special procedure for Groups, systems and procedure packs.

Some of the component devices purchased by *Dryandra Medical* are supplied to it sterile while others are supplied non-sterile. Some of the component devices are purchased from suppliers outside of South Africa and some from suppliers in South Africa.

Dryandra Medical looks at the eligibility requirements for meeting the special procedure and finds that it is eligible to apply it to all of its component devices except for the tubing and gauze, as the component manufacturers of these devices do not hold the appropriate documentary evidence. *Dryandra Medical* therefore chooses to take on the role of the (component) manufacturer just for those components, and assembles appropriate technical files accordingly.

Dryandra Medical then applies for a SA Conformity Assessment Certificate for:

- terminal sterilisation of surgical tubing procedure packs; and
- the component devices where it is assuming the role of component manufacturer.

Once the SA Conformity Assessment Certificate is issued, *Dryandra Medical* applies the special procedure for Groups, systems and procedure packs for the entire procedure pack.

The Applicant then submits the South African Declaration of Conformity that *Dryandra Medical* has completed in accordance with the special procedure as the Manufacturer's Evidence.

Additional requirements of the special procedure

Item	Requirement
Labelling and *Instructions for Use*	The special procedure requires that in addition to the requirements of Essential Principle 13, the *Instructions for Use* must be included for each component item in a system or procedure pack whenever it is provided by the component manufacturer. The Registration number for all component medicines included in the system or procedure pack must be included on the labelling of the system or procedure pack. *Note: As per Essential Principle 13.3(3), manufacturers must provide a list of the contents of the system or procedure pack with the product.*
Declarations of Conformity	System and procedure pack manufacturers using the special procedure should ensure that the Declaration of Conformity is prepared. Manufacturers must identify each item in the package, regardless of whether they are medical devices, medicines etc.. When making a South African Declaration of Conformity, system and procedure pack manufacturers must list the MCC medicines register numbers for all medicines in the pack; however, there is no requirement to list Medical Device registration numbers or GMDN codes for the medical device components. Each medical device component in a system or procedure pack must be used for the intended purpose indicated by the component manufacturer. For example, a blood-collection container cannot be used as a container for a *povidone iodine* solution. A person who wants to change the intended purpose of a medical device becomes the manufacturer of that medical device and must apply appropriate conformity assessment procedures accordingly.
Manufacturer's evidence	Manufacturer's evidence for manufacturers using the special procedure consists of the manufacturer's South African Declaration of Conformity. For systems or procedure packs that are supplied sterile the system or procedure pack manufacturer must hold appropriate QMS certification for the sterilisation processes. Therefore a Manufacturer's Evidence in this case consists of a South African Declaration of Conformity as well as a certificate for the sterilisation processes.
Post-market requirements	In accordance with the special procedure for Groups, systems and procedure packs manufacturers are required to establish a post-market surveillance system to: • systematically review experiences gained after the device is supplied in South Africa • implement any necessary corrective action in relation to the production of the device • notify the Council of adverse events and near miss events • notify the Council as soon as practicable about information relating to malfunction or deterioration of its device • notify the Council as soon as practicable about any inadequacy in the production, labelling, *Instructions for Use*, or advertising materials of its device • notify the Council as soon as practicable about any use the device that might lead to, or might have led to, the death or serious deterioration of the health of a patient or user of the device • notify the Council as soon as practicable about any information relating to technical or medical reasons that have led the manufacturer to recover the device for any of the reasons outlined above.

11.9 SPECIFIC TYPES OF GROUPS, SYSTEMS AND PROCEDURE PACKS

Case	Description
Subsets of systems or procedure packs	If a system or procedure pack contains a large number of items, the prospective holder of the registration certificate can supply systems or procedure packs that contain a subset of these items without additional SA Medical Device Register inclusions, provided that the subsets of the system or procedure pack are of the same kind of medical device, that is, the same holder of the certificate of registration, manufacturer, GMDN, and Class.
Sterile procedure packs	If a system or procedure pack is to be supplied sterile, the manufacturer must obtain Conformity Assessment Certification from a Conformity Assessment Body l or an approved Notified Body. The sterilisation process must be appropriate for all medicines and medical devices in the system or procedure pack. This has particular significance where a sterile system or procedure pack contains a pre-sterilised component.
Class D, including systems or procedure packs	If a system or procedure pack is classified as Class D, each model of the system or procedure pack needs to be included on the SA Medical Device Register at the Unique Device Identifier level. Class D Groups, systems and procedure packs will be selected for a mandatory pre-market application audit. If a Conformity Assessment Certificate has only been issued for sterilisation activities then a mandatory application audit will be conducted.
Single-use system or procedure	A single-use system or procedure pack should not be reprocessed for reuse. If a manufacturer of a system or procedure pack has provided instructions for reprocessing of unused components then unused components can be reprocessed according to those instructions.
Reusable system or procedure pack	A reusable system or procedure pack can be reprocessed for reuse if the manufacturer has declared that it can be reused. Any reprocessing should be done in accordance with the manufacturer's instructions.
Medical devices containing materials of animal, microbial, or recombinant origin and medical devices incorporating a medicinal substance	A SA Conformity Assessment Certificate is required for medical devices that incorporate a medicinal substance or that contain materials of animal, microbial, or recombinant origin. For Groups, systems and procedure packs that include such Class D components, the manufacturer may either obtain a Conformity Assessment Certificate fo the system or procedure pack as a whole OR the relevant Class D component only - and then apply the special procedure for the system or procedure pack as a whole. The manufacturer's declaration of conformity would then be lodged as manufacturer's evidence in order to include the system or procedure pack on the SA Medical Device Register.
Component medicine(s) and systems or procedure packs that incorporate other therapeutic items	Groups, systems and procedure packs are classified without considering any medicine or other medicinal components. However, medicinal component or medicines that are incorporated into a system or a procedure pack must meet the regulatory requirements for the medicine or components. The system or procedure pack containing a medicine must also satisfy the labelling requirements for the medicine.

Case	Description
	Where a sterilisation process is used to sterilise a system or procedure pack, the method must be appropriate for all medicines and other components, and medical devices in the system or procedure pack. The additional sterilisation process must be in accordance with the initial approval for the registration of the medicine, that is, an assessment must have been made to determine if the sterilisation process will affect the quality, safety, or efficacy of the medicine.

11.10 CHANGES TO CONTENTS

If the contents in a system or procedure pack change, the system or procedure pack manufacturer needs to reassess:

- the classification
- the GMDN
- the UDI (applicable to Class D only)
- whether the change is covered by the scope of the existing conformity assessment evidence
- eligibility for the special conformity assessment procedures (if applicable), and then
  - apply appropriate conformity assessment procedures
  - update documentation, including the South African Declaration of Conformity

If the changes result in a new GMDN and/or classification then a new application to include the system or procedure pack in the SA Medical Device Register will be required.

11.11 ACCESSORIES

If an accessory to a system or procedure pack is a medical device, and it is supplied separately from the system or procedure pack, it will need a separate registration as a medical device from that of the system or procedure pack.

If the accessory has a different GMDN or Classification to the system or procedure pack, or in the case of Class D a different UDI, it is considered to be a different type of medical device to the system or procedure pack and therefore requires a separate inclusion in the SA Medical Device Register.

12 DESTRUCTION OF MEDICAL DEVICES OR IVDS

Medical devices or IVDs may not be disposed of into municipal sewerage systems.

The destruction or disposal of medical devices and IVDs must be in compliance with the Hazardous Substances Act No 15 of 1973 and the destruction or disposal must be such that they are not retrievable or cannot be re-used or reassembled.

Unused medical devices must be destroyed if any of the following applies:

- the devices have passed their expiry date;
- the devices no longer comply with the essential principles;
- conformity assessment procedures were not applied to the device(s);
- use of the devices poses, or would pose, a risk to public health;
- storage of the devices at their current location and any other location poses, or would pose, a risk to the public or the environment.

12 Destruction of Medical Devices or IVDs - continued

A person who destroys medical devices must ensure that the destruction avoids or minimises harm to the public and the environment.

Records of destruction of Class C and Class D medical devices and IVDs must be retained.

13 NON-RECALL ACTIONS FOR MEDICAL DEVICES

Where a licence holder or the holder of a registration certificate is unsure of the appropriate action to be taken, and particularly in cases where patient safety may be a consideration, the issues involved should be discussed with the Council.

Other action may be taken by the manufacturer or distributor voluntarily that is not considered to be a recall:

Action	Description
Safety Alert	Intended to provide information on safe use of devices, as distinct from recall action, which addresses product deficiencies Are issued to provide additional advice to health professionals in situations where the device, although meeting all specifications and therapeutic indications, its use could present an unreasonable risk of substantial harm if certain specified precautions or advice are not observed. For example, specific precautions about the longevity of an implanted medical device
Product Notification	Issue of precautionary information about a device in a situation that is unlikely to involve significant adverse health consequences
Product Withdrawal	Manufacturer or distributor's removal from supply or use of devices for reasons not related to their quality, safety or performance
Product Recovery	The manufacturer or distributor recovers devices that have been manufactured or imported but not yet supplied to the market. For example, recovery of devices in a warehouse
User information	Generally conducted by the holder of the registration certificate in response to issues with the use of a medical device Includes in-house sessions, seminars and improved educational materials such as posters

Note: Terms such as upgrade notice, market correction, field safety correction that are commonly used by overseas manufacturers and/or regulators may be considered a recall in South Africa.

14 CANCELLATION OF A MEDICAL DEVICES AND REMOVING FROM THE SA MEDICAL DEVICE REGISTER AND IVD REGISTER

The Council may cancel and remove a medical device from the SA Medical Device Register and IVD Register, as follows:

Legislative reference	Description
Section 16 Suspension of kinds of medical devices from the register	The Council may by written notice suspend a device from the SA Medical Device Register and IVD Register if: • there is a unanticipated risk of death, serious illness or serious injury that does not outweigh the benefit of the device if the device continues to be included in the SA Medical Device Register and IVD Register

Legislative reference	Description
	• the Council is satisfied that a statement made in or in connection with the application for including the device in the SA Medical Device Register and IVD Register was false or misleading • the annual fee is not paid as provided by the provisions of the Medicines Act • a conformity assessment certificate (either issued in South Africa or by an overseas regulatory agency or notified body) is suspended • the Medical Device or IVD does not comply with the conditions under which it was registered The Council will: • inform the Holder of Registration Certificate by written notice of the proposed suspension and set out the reasons for it • give the Holder of Registration Certificate an opportunity to make submissions to the Council in relation to the proposed suspension consider any submissions the Holder of Registration Certificate makes before making a decision relating to the proposed suspension

UPDATE HISTORY

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12 Dec 2014	Due date for comment	
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