MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

APPLICATION FOR REGISTRATION OF A MEDICAL DEVICE [1]
ZA CH1.04: Administrative Information
Application Form

This application form will be included in the South African Technical Document – Chapter 1 Regional Administrative Information.

The application form is to be used for an application for registration of a medical device for human or animal use submitted to the South African Regulatory Authority.

A separate application form for each type or "family" or "group" of medical device is required.

"**family**" means a medical device or IVD comprising of the same type of medical device available in different models and sizes.

"**group**" means a medical device or IVD comprising of a collection of medical devices or IVDs such as a procedure pack, procedure tray, system or procedure kit, that are packaged together for a specific intended purpose and sold under a single name.

a) Particulars of the Applicant/Prospective holder of the certificate of registration (PHCR)

Name:	
Business address:	
Postal address:	
Telephone no:	
Fax no:	

[1] Read together with the definition in Act 101 of 1965 as amended

E-mail address:	
Quality Manual File Reference Number:	

Authorised Representative to communicate with SA Regulatory Authority	
Name:	
Business address:	
Telephone no:	
Fax no:	
E-mail address:	
☐ ***(Attach a letter of authorisation signed by the person responsible for the overall management and control of the business – Annex 1.04.01.01***	

b) Particulars of the medical device or IVD

Product	
IVD or Non-IVD:	
Proprietary / trade mark name:	
GMDN Code number:	
GMDN Term definition:	
GMDN Term name:	
For combination medical devices: Name(s) of scheduled substances	
[2]*Approved name(s):*	
Strength(s) per dosage unit:	
Descriptive name of Biological medicine:	
Country of origin (country in which the original development was carried out):	

[2] Only one name per API in the product should be given: The International Non-proprietary Name (INN) accompanied by its salt or hydrate form (if relevant), or chemical description of the API(s)

c) Type of medical device

Indicate the type of medical device, using a check mark (✓) or a cross (X):

(more than one check mark or cross may be relevant on a row, but only ONE class can be applicable)

Type of medical device→ / ***Class of medical device↓***	***Measuring medical device***	***Sterile medical device***	***Blood storage or blood transportation device***	***Non-invasive***	***Invasive medical device***			***In-active***	***Active***	***Contra-ceptive***	***Combination medical device***	***IVD***
					< 60 min	≥ 60 min & ≤ 30 days	> 30 days					
A												
B												
C												
D												
RUO[3] (IVD)												

[3] Research Use Only

d) Manufacturing information

Manufacturing, packaging, testing sites[4] in South Africa	
Manufacturer(s)*:*	
Physical address of site(s):	
Quality Manual reference number(s):	
Date of submission	
Medical Device Establishment Licence number:	
Date of issue:	

Primary Packer(s)*:*	
Physical address of site(s):	
Quality Manual reference number(s):	
Date of submission	
Medical Device Establishment Licence number:	
Date of issue:	
Secondary Packer(s):	
Physical address of site(s):	
Quality Manual file reference number(s):	
Date of submission:	
Medical Device Establishment Licence number:	
Date of issue:	
Finished product release control (FPRC)(s)*:*	
Physical address of site(s):	
Quality Manual reference number(s):	
Date of submission:	
Medical Device Establishment Licence number:	
Date of issue:	

[4] If more than one site is involved, clearly identify the site for *each* stage.

***Finished product release responsibility (FPRR)(s)**:*	
Physical address of site(s):	
Quality manual reference number(s):	
Date of submission:	
Medical Device Establishment Licence number:	
Date of issue:	
Technical service workshop(s)	
Physical address of site(s):	
Quality Manual reference number(s):	
Date of submission	
Medical Device Establishment Licence number:	
Date of issue:	

☐ *It is hereby confirmed that copies of the latest ISO 13485 certificate for manufacturer(s) and packer(s) and/or a copy of the appropriate manufacturing licence(s) have been included in CH1.06*

If an ISO13485 certificate is not available, details of a relevant quality management system, with supporting evidence, must be included.

e) Declaration and signature

The undersigned hereby declares that all the information herein, and in the Annexes and Chapters hereto, are correct and true and are relevant to this particular medical device, and that all existing data which are relevant to the quality, safety and performance of the medical device have been supplied in the dossier, as appropriate.

☐ *It is hereby confirmed that fees have been paid according to current legislation, and proof is attached in CH 1.08*

.....…….. *.....……...*
Signature of Authorised Representative [Section a) above] *Date of application*

..... *.....……...*
Name in block letters *Date of registration*

..... *……..…….....*
Designation *Date of current amendment*

f) Type of application

NEW APPLICATION

Indicate the type of medical device, and the type of data included as proof of safety & performance, using a check mark (✓) or a cross (X):

i) Human Medical Device: (Non-IVD)				***Evidence of Conformity Assessment:***	
Class A sterile		*New technology*		*South African Declaration of Conformity to the Essential Principles of Safety and Performance as per the Conformity Assessment Guideline*	
Class A measuring		*A predicate exists*			
Class B		*Line extension*			
Class C		*Call Up*		*Full Quality Assurance Management System Certificate*	
Class D		*Amendment*			
Combination Medical device:				*ISO13485: 2008 Certificate*	
Medical device & medicine / scheduled substance				*ISO13485:2016 Certificate*	
Medical device & biological				*Product Quality Assurance Certificate(s)*	
Other (provide details)				*Production Quality Assurance Certificate(s)*	

A "predicate medical device" is a medical device which is on the Register of Medical Devices and to which substantial equivalence is drawn.

A device is substantially equivalent if, in comparison to a predicate, it:

- *has the same intended use as the predicate;* ***and***
- *has the same technological characteristics as the predicate;*
  or
- *has the same intended use as the predicate;* ***and***
- *has different technological characteristics and the information submitted to MCC / SAHPRA,*
  - *does not raise new questions of safety and effectiveness;* ***and***
  - *demonstrates that the device is at least as safe and effective as the legally marketed device.*

A claim of substantial equivalence to a predicate medical device does not mean the device(s) must be identical. Substantial equivalence is established with respect to: intended use, design, energy used or delivered, materials, performance, safety, effectiveness, labeling, biocompatibility, standards, and other applicable characteristics.

ii) Human IVD:				***Evidence of Conformity Assessment:***	
Class B		*New Technology*		*South African Declaration of Conformity to the Essential Principles of Safety and Performance as per the Conformity Assessment Guideline*	
Class C		*A Predicate exists*			
Class D		*Line Extension*			
RUO IVD		*Call up*		*Full Quality Assurance Management System Certificate*	
		Amendment			
				ISO13485: 2008 Certificate	
				ISO13485:2016 Certificate	
				Product Quality Assurance Certificate(s)	
				Production Quality Assurance Certificate(s)	

iii) Veterinary Medical Device: (Non-IVD)				***Evidence of Conformity Assessment***	
Class A sterile		*New technology*		*South African Declaration of Conformity to the Essential Principles of Safety and Performance as per the Conformity Assessment Guideline*	
Class A measuring		*A Predicate exists*			
Class B		*Line extension*			
Class C		*Call up*		*Full Quality Assurance Management System Certificate*	
Class D		*Amendment*			
Combination Medical device:				*ISO13485: 2008 Certificate*	
Medical device & medicine / scheduled substance				*ISO13485:2016 Certificate*	
Medical device & biological				*Product Quality Assurance Certificate(s)*	
Other (provide details):				*Production Quality Assurance Certificate(s)*	

iv) Veterinary IVD:				***Evidence of Conformity Assessment***	
Class B		*New technology*		*South African Declaration of Conformity to the Essential Principles of Safety and Performance as per the Conformity Assessment Guideline*	
Class C		*A predicate exists*			
Class D		*Line Extension*			
RUO IVD		*Call-up*		*Full Quality Assurance Management System Certificate*	
				ISO13485: 2008 Certificate	
				ISO13485:2016 Certificate	
				Product Quality Assurance Certificate(s)	
				Production Quality Assurance Certificate(s)	

For multiple / duplicate applications of the same medical devices	
Proposed Proprietary Name(s) of the other product(s):	
Date of application(s) (yyyy-mm-dd):	

AMENDMENT/VARIATION

Indicate the type of amendment/variation using a check mark (✓) or a cross (X):

Post-registration:		***Response to pre-registration recommendation:***	
Non-IVD medical device		*Non-IVD medical device*	
IVD		*IVD*	
Proprietary Name		*Proprietary Name*	
Inspectorate		*Inspectorate*	

g) Responsible person for Vigilance

Name:	
Business address:	
24 Hour Telephone no:	
Fax no:	
E-mail address:	
(Attach CV – Annex 1.04.1.3)	

h) Amendment history

Date of letter of amendment application	*Summarised details of amendment*	*Date of Regulatory Authority response*

UPDATE HISTORY

Date	Reason for update	Version & publication
June 2017	First publication released for comment	Version 1, Aug 2017
31 October 2017	Due date for comment	