SAHPRA
South African Health Products Regulatory Authority

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

Communication to Stakeholders 22 July 2020

MD020: Application for a Certificate of Free Sale for Medical Devices

BACKGROUND

1. The Medicines and Related Substances Act, 1965 (Act 101 of 1965) read in conjunction with the General Regulations on Medical Devices, published in Government Gazette Notice 40480, No.1515 of 09 December 2016, provides for the regulatory oversight of Medical Devices including In-Vitro Diagnostics (IVDs) in South Africa.

2. A Certificate of Free Sale is a certificate, issued by the South African Health Products Regulatory Authority (SAHPRA), which serves as confirmation that the listed medical devices are legally sold or distributed in the open market in South Africa, freely without restriction, and approved by the regulatory authority (SAHPRA) in the country of origin (South Africa).

3. A Certificate of Free Sale may be referred to as a "Certificate for Export" or "Certificate to Foreign Government" in other jurisdictions.

4. A Certificate of Free Sale may only be issued to a SAHPRA medical device establishment licence holder, who is authorised by SAHPRA to manufacture medical devices.

5. The Certificate of Free Sale serves as confirmation by SAHPRA that the manufacturer is:
   - the legal original manufacturer; and
   - licensed by SAHPRA to manufacture the medical device/s.

   Note: the medical device/s has/have not been assessed for safety and performance by SAHPRA.

6. Certificates of Free Sale aim to **meet the needs of the importing country.** Before applying for a certificate SAHPRA recommends that the applicant contact the relevant foreign government through their consulate to ascertain what information must be supplied in order to facilitate the export of the medical devices to their country.

7. Only medical device/s that are listed in Sections 4.1, 4.2, 17.1 and/or 17.2 of the current SAHPRA licence application of the manufacturer, are eligible for inclusion in the application for a certificate of free sale.

8. The application for a Certificate of Free Sale may include multiple medical devices and multiple recipient countries. It is not necessary to apply for a certificate of free sale for each listed medical device and/or recipient country.

9. The Certificate of Free Sale will be valid for a maximum period of one year and will be void when medical device/s are called up for registration, in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965.

REQUIRED INFORMATION

10. The following documents must be submitted upon application to SAHPRA for a Certificate of Free Sale:
    a. Cover letter on a company letterhead indicating intention to apply for a Certificate of Free Sale. ***NOTE: the subject of the letterhead should state: RE: APPLICATION FOR A CERTIFICATE OF FREE SALE***
    b. The completed Certificate of Free Sale Application Form (Annex 1);
    c. A copy of a valid SAHPRA medical device establishment licence to manufacture medical devices;
    d. Product listings, included in the current SAHPRA licence application of the manufacturer, for medical devices and IVDs manufactured in South Africa, as provided in section 4.1 and 4.2 respectively and exported as provided in section 17.1 and 17.2;
    e. Proof of payment;
    f. For medium to high risk (Class C) and high risk (Class D) medical devices listed in the Certificate of Free Sale application:
        i. Evidence of pre-market approval/registration/evidence of emergency use authorisation for each listed medical device/s from at least one of the six jurisdictions recognised by SAHPRA (Australia, Brazil, Canada, Europe, Japan, United States of America) or pre-qualification by the World Health;
        ii. Evidence of ISO13485 certification of the original manufacturer;
        iii. Declaration that medical device/s manufactured are safe and perform as intended and that the medical device/s fulfils the Essential Principles of Safety and Performance for Medical Devices.

SUBMISSION OF APPLICATION AND TIMELIMES

11. Applications must be submitted via email to **mdadmin@sahpra.org.za.**

12. The fee for a Certificate of Free Sale is payable upon application and proof of payment should be submitted together with the completed application. ***Note: Fees may be updated from time to time. The onus is on the applicant to ensure that payment is made in line with the current fees structures, as published in the Government Gazette.***

13. Payments should be made as per 17.02 Guideline for the direct transmission of fees payable to SAHPRA.

14. The Certificate of Free Sale application process will completed within fifteen (15) days from the date of submission of the application, provided that the application submitted is complete and meets the requirements.
    Note: Incomplete applications will be returned to the applicant. Please ensure that on submission to SAHPRA all relevant fields are completed and all supporting documentation is attached.

INFORMATION APPEARING ON A CERTIFICATE OF FREE SALE

15. The following information will be included on the Certificate of Free Sale:
    - Name, site address, licence number and MDF number of SAHPRA licensed manufacturer of medical device
    - Details of medical device/s intended for export and listed in this application including
        - GMDN code
        - GMDN descriptor
        - Name and/or group and/or family of the medical device
        - South African risk class of medical device
        - Recipient Country/ies
    - Name and contact details of the authorised representative
    - Any additional particulars required to facilitate the export of the listed medical device/s to the relevant foreign government.

DR B SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER OF SAHPRA
22 JULY 2020

ANNEX 1: CERTIFICATE OF FREE SALE APPLICATION FORM

APPLICATION FOR CERTIFICATE OF FREE SALE FOR MEDICAL DEVICES	
PART A:	**DETAILS OF APPLICANT (SAHPRA LICENCE HOLDER)**
Company Name:	
Licence Number:	
MDF Number:	
Site Address:	

PART B:	**DETAILS OF AUTHORISED REPRESENTATIVE**
Name:	
Contact Number:	
Email:	

PART C:	**DECLARATION BY AUTHORISED REPRESENTATIVE**
Applicants should note that in terms of the provisions of the Medicines and Related Substances Act 101, 1965 (Act 101 of 1965) as amended, it is an offence to make false and misleading statements in connection with an application for a certificate of free sale.	
1. I declare that the company is a holder of a valid SAHPRA medical device establishment licence to manufacture medical devices.	
2. I declare that the medical device/s listed in this application form are available for legal sale or distribution in the open market in South Africa, freely without restriction, and meet the relevant SAHPRA regulatory requirements in the country of origin (South Africa).	
3. I declare that the medical device/s manufactured and listed in this application form are safe and perform as intended and that the medical device/s fulfils the Essential Principles of Safety and Performance for Medical Devices and IVDs.	
4. Full technical documentation is available for the Class C and/or Class D medical device/s listed in the application.	
5. I further declare that all information contained in this application form, and in the documents attached, is true and correct at the date of signing.	
Signature of Authorised Representative	
Name:	
Date:	

PART D:	**DETAILS OF MEDICAL DEVICE/S INTENDED FOR EXPORT**			
GMDN Code	GMDN Descriptor	Name and/or Group and/or Family of the medical device	Risk Class of medical device	Recipient Country/ies
Recipient Country/ies		Additional particulars required to facilitate the export		