SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Road
Arcadia
0083

Communication to Stakeholders **August 2023**

MD038: SAHPRA position on EU regulatory transition for medical devices from MDD/AIMDD/IVDD to MDR 2017/745 /IVDR 2017/746

Regulation in terms of the Medicines and Related Substances Act 101, as administrated by the Medical Devices Operational Unit of SAHPRA:

The Medicines and Related Substances Act 101 as amended, section 22C. (1)(b) requires a medical device establishment to hold an establishment licence issued by SAHPRA, in recognition of the activities conducted by the organisation. Such a licence is issued upon the fulfilment of the regulatory requirements which include, but are not limited to, listing of the medical devices in the application form and holding evidence of an "originating approval" as noted in SAHPRA Guideline for a licence to manufacture, import, export or distribute medical devices & IVDs, https://www.sahpra.org.za/wp-content/uploads/2023/03/SAHPGL-MD-06_v3-Guideline-for-A-License-to-Manufacture-Import-Export-or-Distribute-Medical-Devices-and-IVDs.pdf

For a medium to high risk (Class C) and high risk (Class D) medical device proof of such an "originating approval" (i.e., premarket approval or registration) for the medical device, including an IVD, from at least one of the six recognised jurisdictions, or from WHO Prequalification for an IVD, is required.

The European Union's Conformité Européenne certificate, referred to as a CE certificate, to show conformity of a medical device, including IVD, to all regulatory obligations as required in the European Union, is one of the "originating approvals" Recognised by SAHPRA.

For a low to moderate risk (Class B) and moderate to high risk (Class C) and high risk (Class D) medical device, including an IVD, a Certificate of Free sale from the country of manufacture or final assembly is also required by SAHPRA. The certificate of free sale is evidence that the medical device is legally sold or distributed in the open market, freely without restriction, and approved by the regulatory authorities in the country of origin.

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No product may be imported into South Africa without a medical device establishment licence as per Section 22C (6) of the Medicines and Related Substances Act 101 of 1965 (as amended).

For enquiries, kindly contact the medical device unit by emailing to mdqueries@sahpra.org.za

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Regulation in terms of the Hazardous Substances Act 15 of 1973, as administered by the Radiation Control Operational Unit of SAHPRA:

Section 4 (1) c of the Hazardous Substances Act 15 of 1973 and Regulation 1302 , notes that the Director-General may on application in the prescribed manner and on payment of the prescribed fee (if any) and subject to the prescribed conditions and such further conditions as the Director-General may in each case determine, issue to any person a licence (c) to install a Group III hazardous substance on any premises mentioned in such licence . Individuals applying for such licence are required to provide a valid CE certificate.

To address the extension period in accordance with EU commission MDR 2017/745 amendment, a company or individual applying for a new import license and submitting annual compliance information for a licensed medical device must submit the following in addition to the current requirements, unless a model is covered by a valid CE certificate issued in accordance with Directive 90/385/EEC, 93/42/EEC or MDR 2017/745/EU:

i. A confirmation letter issued by the MDR Notified Body stating the receipt of the manufacturer's application for conformity assessment and the conclusion of a written agreement. The confirmation should clearly identify the medical device covered by the extension and certificates concerned.

ii. A Self-Declaration by the manufacturer of the medical device confirming that the conditions for the extension are fulfilled, stating the end date of the transition period. The self-declaration should clearly identify the medical device covered by the extension and certificates concerned.

For enquiries, kindly contact the Radiation Control unit by emailing to nirmed.enquiry@sahpra.org.za The authority acknowledges and aligns with the EU transition and the timelines allocated, albeit that there are still concerns regarding the implementation, more information can be found on the following link: https://health.ec.europa.eu/system/files/2023-07/thirdcountries_factsheet_en_0.pdf

For enquiries; kindly regarding Radiation Control

Digitally Signed by:
Boitumelo Semete-Makokotlela
Chief Exective Officer
53e72d92-3391-4cd7-8da3-b6116e65c520

Dr B SEMETE-MAKOKOTLELA

CHIEF EXECUTIVE OFFICER OF SAHPRA

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