South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

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GUIDELINE FOR LICENCE APPLICATIONS FOR NON-IONISING RADIATION MEDICAL AND NON-MEDICAL DEVICES CLASSIFIED AS LISTED ELECTRONIC PRODUCTS

This guideline is intended to guide applicants wishing to submit applications for the listed electronic products. It represents the South African Health Products Regulatory Authority's (SAHPRA)'s current thinking on the safety, quality, and performance of the listed electronic products.

It is not intended as an exclusive approach. The Authority reserves the right to request any additional information to establish the safety, quality, and performance of the listed electronic products 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 Authority is committed to ensuring that all registered listed electronic products meet the requirements of the essential principles relating to 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 SAHPRA website.

Document History

Final Version	Reason for Amendment	Effective Date
1	First issue	September 2024

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

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Glossary

Abbreviation/ Term	Meaning
Notified Body	A Notified Body is an organisation designated by an EU Member State (or by other countries under specific agreements) to assess the conformity of certain products before being placed on the market. The Notified Body is entitled to carry out tasks related to conformity assessment procedures set out in the applicable legislation when the intervention of a third party is required.
Listed product	It is an electronic product which has been declared a Group III Hazardous Substance in terms of section 2(1)b and 3(b) by the Minister, by notice in the Gazette. This is in terms of the Hazardous Substances Act no. 15 of 1973.
Importer	It is any person who, whether as owner, consignor, consignee, agent, or broker, has or is in any way entitled to the custody or control of any Group III hazardous substance imported.
Manufacturer	It is any person who, whether as owner, consignor, consignee, agent, or broker, has or is in any way entitled to the custody or control of any Group III Hazardous Substance assembled, produced, prepared, processed, repaired, or the use of any other manufacturing or maintenance process.
Declaration of Conformity	The Declaration of Conformity is a legal document in which the manufacturer or authorised representative signs to state that all CE Marked products sold in the European Union, meet all of the requirements of the applicable EU Directives and Regulations.
Group III Hazardous Substance	Devices producing ionising radiation, e.g. X-rays, devices producing non-ionising radiation, e.g. lasers, ultraviolet, infrared, RF, ultrasound and High and Medium risk electromedical devices.
MDD 93/42/EEC	The Medical Device Directive (of 14 June 1993) concerning medical devices is intended to harmonise the laws relating to medical devices within the European Union. For a manufacturer to legally place a medical device on the European market, the requirements of the MD Directive have to be met. Manufacturers' products meeting harmonised standards' have a presumption of conformity to the Directive. Products conforming to the MD Directive must have a CE mark applied.
MDD 90/385/EEC	The Active Implantable Medical Devices Directive applies only to active implantable devices. For a device to be classified as an active implant, it must rely on a power source not provided by the body or gravity and be designed to be introduced into the body with the intention to remain there following the procedure.
MDR 2017/745/EU	It is a Regulation of the European Union on the clinical investigation and sale of medical devices for human use. It repeals MDD 93/42/EEC, which concerns medical devices, and Directive 90/385/EEC, which concerns active implantable medical devices, on 26 May 2021. The regulation came into force on 25 May 2017. Originally approved medical devices had a transition time until 26 May 2021 to meet new requirements. MDD certificates will be valid until their original expiry date or 26 May 2024, whichever is sooner. This is if compliance is maintained, certain elements of the MDR are fulfilled, and the Notified Body performs surveillance activities. Thus, manufacturers can continue to put MDD-certified devices on the market up to and including 26 May 2024.

NIRMED	Non-Ionising Radiation and Medical Devices
EU	European Union

1. INTRODUCTION

The selling, letting, use, application, installation, manufacturer, and importation of the scheduled list of electronic products are subject to control in terms of Section 4(1)(b) of the provisions made by the Hazardous Substances Act, 1973 (Act 15 of 1973) and subsequent regulations.

The intent of the Non-Ionising Radiation and Medical Devices (NIRMED) subdivision under Radiation Control in terms of the license application for listed electronic products is to ensure that SAHPRA remains abreast of the following:

- The manufacturers of listed electronic products in South Africa.
- Importers and distributors of listed electronic products in South Africa.
- The technical review criteria of import applications for listed electronic products into South Africa.

1.1 Purpose

- To ensure the safety of the public by controlling certain electronic products in terms of the Hazardous Substances Act, Act 15 of 1973 and subsequent regulations.
- To ensure the submitted applications of the listed electronic products are compliant.

1.2 Scope

- To guide the applicant on the license application process for the listed electronic products.
- To guide the applicant on the minimum requirements for import license applications for listed electronic products.
- To be consistent with the Hazardous Substances Act 15 of 1973.

2. LEGAL PROVISION

- To control the importation of certain electronic products according to the Hazardous Substances Act number 15 of 1973.
- The licensing for sale, let, and use of listed electronic products according to Regulation number R.690 of 1989.
- The schedule of listed electronic products according to Regulation number R.1302 of 1991.

3. LIST OF APPLICATION FORMS

Title	Document Number
Application for a licence to import a new listed electromedical product	GLF-RDN-NM-01A (Old Form No. 41BM-1(IMP))
Application for a licence to import a new listed non-medical product	GLF-RDN-NM-01B (Old Form No. 41BN-1(IMP))
Application for a licence to manufacture a listed electromedical product in SA	GLF-RDN-NM-01C (Old Form No. 41BM-1(MAN))
Application for a licence to manufacture a listed non-medical product in SA	GLF-RDN-NM-01D (Old Form No. 41BN-1(MAN))

4. APPLICATION FOR THE LICENCE TO IMPORT OR MANUFACTURE OF LISTED ELECTRONIC PRODUCTS

4.1 A correct application form (www.sahpra.org.za) for either import or manufacture must be submitted to nirmed.application@sahpra.org.za.

4.2 Documents required

The following information will inter alia be reviewed when a licence application is evaluated:

4.2.1 **Licence application forms**

- Complete name of company or individual (not only “trade as” name)
- The company premises street address
- Brand and model name according to the EC Declaration of Conformity
- Indication for use as per brochure
- Details of manufacturer as per brochure and EC (European Union) Declaration of Conformity
- Name of the Authorised Representative in the EU if the manufacturer is not situated in the EU
- Contact person in South Africa with email address and at least one telephone number
- Application form signed and dated (within a week from sent date)

4.2.2 **Brochures with technical specifications**

- Brochure for the specific model as per licence application
- Details of the manufacturer on the brochure
- Technical specifications for the specific model
- Picture of the device

4.2.3 **Agency letter**

- Official letter from the manufacturer authorising the importer to be the official distributor of their product(s)
- Wording to the effect that the importer is a SA agent or representative for the manufacturer

- Signed and dated (or company stamped)

4.2.4 **Notified Body certificate**

- Certificate issued by a recognised Notified Body in the EU
- Certificate issued for the manufacturer as per the application
- Scope of certificate as per the indication for use
- Conformity assessment procedure according to the correct annexure(s)
- Validity period of the certificate
- Certificate verified via Notified Body database, QR code or direct contact with the Notified Body

4.2.5 **Declaration of Conformity**

- Details of the manufacturer
- Declaration statement for the applicable EC Directive(s)/EU Regulation(s)
- Notified Body details
- EU representative details
- Details of specific model as per application form
- Dated and signed (or company stamped)

4.3 **In a case where information in section 4.2.1 – 4.2.5 is not submitted or/and is incorrect:**

- Any application submitted without an application form will be rejected.
- Any application submitted with an incorrect application form will be rejected.
- The applicant will be contacted to correct any omissions and resubmit the correct application form along with the required documents (stated in section 4.2.1 – 4.2.5).
- The applicant must resubmit the correct application form along with the required documents to nirmed.applications@sahpra.org.za.
- The applicants who have submitted invalid supporting documents will be given 10 working days to resubmit the correct supporting documents. Failure to submit valid supporting documents will result in a rejection.

4.4 The turnaround time for the application of an import licence is 50 working days.

5. REFERENCE

The following related document are referenced:

- The Medical Device Directive (MDD 93/42/EEC)
- The Active Implantable Medical Device Directive (MDD 90/385/EEC)
- The Medical Devices Regulation (MDR 2017/745/EU)

6. VALIDITY

This guideline is valid for a period of five (5) years from the effective date of revision. It will be reviewed on this timeframe or as and when required.