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

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# GUIDELINE FOR IMPORT APPLICATIONS OF ELECTRONIC DEVICES EMITTING IONIZING RADIATION

This guideline sets out the requirements and recommendations when applying for a license to import any electronic device emitting ionizing radiation. The Hazardous Substances Act (Act 15 of 1973).

## Document History

| Final Version | Reason for Amendment | Effective Date [dd Month yyyy] |
|---|---|---|
| 1 | First issue and implementation | Mar 2023 |
| 2 | | |

**DR BOITUMELO SEMETE-MAKOKOTLELA**
**CHIEF EXECUTIVE OFFICER**

# Contents

## Glossary

| Abbreviation/ Term | Meaning |
|---|---|
| ACT | Hazardous Substances Act, 1973 (Act 15 of 1973) |
| ASOCI | Annual Submission of Compliance Information |
| CE marking | This is the manufacturer's declaration that the medical device meets the appropriate regulatory requirements. |
| CIPC | Companies and Intellectual Property Commission |
| Doc | Declaration of Conformity |
| EC | European Conformity |
| EC Directive 93/42/EEC | Applies for the placing on the market and launching of medical devices and their accessories |
| EEC | European Economic Community |
| EU | European union |
| Ionizing Radiation | means radiation emanating from a listed electronic product, capable of producing ions directly or indirectly in its passage through matter, |
| MDR | Medical Device Regulation |
| MDD | Medical Device Directive |
| Notified Body | A notified body is an organization designated by a European Member State (or by other countries under specific agreements) to assess the conformity of certain products before being placed on the market |
| Pre-owned | It has been owned by someone else and is sold or transferred to someone else |
| Refurbisher | Refer to a person or company that refurbishes listed electromedical device from pre-owned devices and wish to sell and distribute such devices for use in various industries. |
| SAHPRA | South African Health Products Regulatory Authority |
| X-Ray | means an electronic product which is designed, manufactured, or assembled with the primary purpose of producing X-rays or which utilises X-rays to accomplish its primary purpose and from which such emissions are intended. |

# 1. INTRODUCTION

This guideline prescribes the procedures to be followed, forms to be completed and other requirements to be complied with relating to a license application for import of electronic devices emitting ionizing radiation as promulgated by the Hazardous Substances Act, Act 15 of 1973. Applications for import are guided by the intended use of the device and may include devices or components used for medical and/or non-medical purposes. The requirements for import of device for medical use differs from the requirements for import of devices for non-medical uses as outlined by this guideline.

## 1.1 Purpose

To protect all South African citizens against the known hazardous effects of ionising radiation produced by electronic products without unduly limiting the beneficial applications of these technologies, and to exclude non-compliant electro-medical devices from the South African market.

## 1.2 Scope

This guideline sets out the requirements and recommendations when applying for a license to import any electronic device emitting ionizing radiation used in the medical, dental, veterinary, and industrial industries.

# 2. LEGAL PROVISION

The guideline is implemented in promulgating the Hazardous Substances Act 15, 1973 (Act15 of 1973) and Schedule of Listed Electronic Products (Regulation R1302, 14 June 1991).

# 3. REQUIREMENTS AND RECOMMENDATIONS

## 3.1 LICENSING

The Hazardous Substances Act, Act 15 of 1973 allow for the regulation of electromedical and electronic devices emitting ionizing radiation. In terms of the Schedule of Listed Electronic Products (Regulation R1302, 14 June 1991), electronic products generating X-rays or other ionizing beams, electrons, neutrons, or other particle radiation, must be registered for import.

SAHPRA reserves the right to request any additional information to establish the safety, quality, and performance of a device in keeping with the knowledge current at the time of evaluation, with the aim of issuing an import license. The importation of any pre-owned listed electromedical device is strictly prohibited. Only electromedical devices, which had already previously been licensed either for import into or manufacture in South Africa and which had subsequently been distributed and used within South Africa, may be resold within South Africa.

## 3.2 TYPE OF APPLICATION FORMS AND SUPPORTING DOCUMENTS

List of current application forms:

- 41BM-1 (IMP) New GLF-RDN-XR-24C
- 41BN-1 (IMP) New GLF-RDN-XR-24F
- 41BM-1 (MAN) New GLF-RDN-XR-24D
- 41BN-1(MAN) New GLF-RDN-XR-24G
- 41BM-1 (REFURB) New GLF-RDN-XR-24E
- 41BM-1 (CLINIMP) New GLF-RDN-XR-24A
- 41BM-1 (CLINLOC) New GLF-RDN-XR-24B

The application forms can be downloaded using the following link: https://www.sahpra.org.za/radiation-control-application-and-report-forms/

- Submit one application per email.
- List the name of the applicant and model in the subject field of the email,
- Ensure that all required documentation as listed on the 41BM(IMP) or 41BN(IMP) application forms have been submitted.
- Complete your application in full as incomplete applications will be returned,
- Kindly refrain from pre-dating your application form,
- Completed application forms and required documents must be submitted to the following email address import.xrays@sahpra.org.za

Please allow 4-6 weeks for processing of your import application; the 4-6 weeks' timeline is on condition that all required documentation have been submitted.

### 3.2.1 GLF-RDN-XR-24C (old 41BM-1(IMP))

A medical device can be defined, but not limited to any instrument, apparatus, appliance, material, software, or other article intended by the manufacturer to be used in human beings for the detection, treatment, alleviation or prevention of disease, injury, or disability. Applicants wishing to import electronic devices generating ionizing radiation for use in the medical and dental industries must complete form GLF-RDN-XR-24C (old 41BM-1(IMP)).

### 3.2.2 GLF-RDN-XR-24F (Old 41BN-1(IMP))

Applicants wishing to import electronic devices generating X-rays or other ionizing beams, electrons, neutrons, or other particle radiation outside of the medical and dental industries, including for research purposes, must complete form 41BN-1, and comply with relevant requirements listed in section 3.3.

### 3.2.3 GLF-RDN-XR-24D (Old 41BM-1 (MAN))

Applicants wishing to manufacture medical devices inside the borders of South Africa must complete form 41BM-1(MAN) and comply with relevant requirements listed in section 3.3.

### 3.2.4 GLF-RDN-XR-24G (Old 41BN-1(MAN))

Applicants wishing to manufacture electronic devices for use outside the medical and dental industries, including for research purposes, inside the borders of South Africa must complete form 41BN-1(MAN), and comply with relevant requirements listed in section 3.3.

### 3.2.5 GLF-RDN-XR-24E (Old 41BM-1(REFURB))

Applicants wishing to import a listed electromedical device that has been fully refurbished overseas must complete form 41BM-1(REFURB) and comply with relevant requirements listed in section 3.3.

**Please note:**

In the case where a pre-owned listed electromedical device has been fully refurbished overseas, the requirements for a license to import such a device are basically the same as those for importing a new listed electromedical device.

If a listed electromedical device has been fully refurbished overseas, that fact must be indicated explicitly by serial number in the accompanying EC documentation. The model's name of the affected units must be altered permanently on the units themselves to reflect the fact that these are indeed refurbished units.

If a listed electromedical device has been refurbished overseas for the explicit purpose of distributing or using it locally as a non-medical device, e.g., for veterinary use, that device may not be imported under its original brand- & model name. The refurbisher must give the device a completely new name that bears no resemblance to the original brand- & model name (which, in turn, must be removed completely and permanently). The new name must be affixed to the device permanently and indelibly and must also be reflected in the instructions for use and any associated promotional materials.

### 3.2.6 GLF-RDN-XR-24A (Old 41BM-1 (CLINIMP))

If the intention is to conduct clinical trials using a listed electromedical product that is imported into South Africa for commercial distribution, form 41BM-1 (CLINIMP) must be completed in full and submitted with relevant requirements listed on the form and in section 3.3.

### 3.2.7 GLF-RDN-XR-24B (Old 41BM-1 (CLINLOC))

If the intention is to conduct clinical trials using a listed electromedical product that is manufactured in South Africa, form 41BM-1 (CLINLOC) must be completed in full and submitted with relevant requirements listed on the form and in section 3.3.

## 3.3 REQUIREMENTS AND SUPPORTING DOCUMENTS

### 3.3.1 Primary Importer in South Africa

The primary importer in South Africa is the natural person in contact with the international manufacturer for importing of their devices to South Africa. It is the duty of the primary importer to comply with the requirements and stipulations of the Hazardous Substances Act, Act 15 of 1973, as well as any conditions as determined by SAHPRA.

### 3.3.2 Companies and Intellectual Property Commission

Is an agency of the Department of Trade and Industry in South Africa.[1] The CIPC was established by the Companies Act, 2008 (Act No. 71 of 2008)[2] as a juristic person to function as an organ of state within the public administration, but as an institution outside the public service. https://www.cipc.co.za/

### 3.3.3 Manufacturer

A manufacturer is a person or company that produces finished goods from raw materials by using various tools, equipment, and processes, and then sells the goods to distributors or to other manufacturers to produce more complex goods.

### 3.3.4 Technical File

A technical file is a set of documents that describes a product and can prove that the product was designed in accordance with the requirements of a quality management system All products that have a CE mark must have a technical file which must contain the information that proves that the product conforms with the EU directives and regulations for CE-marked products. Regulatory Authorities may demand a copy of the technical file for regulatory purposes. The technical file must be available for many years after the last product was made.

### 3.3.5 Product Information

The brand and model of the device being considered must be specified for identification purposes. A color brochure including technical specifications of the model being considered for import must therefore accompany your completed application form.

### 3.3.6 Refurbisher

A refurbisher is a person or company that refurbishes listed electromedical device from pre-owned devices and wish to sell and distribute such devices for use in various industries.

### 3.3.7 Authorized representative in the European Union

An authorized representative is defined as being any natural or legal person established within the European Union who has received and accepted a written mandate from a manufacturer located outside the EU, to act on the manufacturer's behalf in relation to specified tasks regarding the latter's obligations under the Regulations (*https://eumdr.com/authorised-representatives* ).

### 3.3.8 Company contacts person in South Africa

The contact person in South Africa for all regulatory correspondence. Only one person per company is allowed - not multiple contact persons. Responsibility of license holder to update contact person details with SAHPRA where necessary.

### 3.3.9 Letter authorizing sale in South Africa

Documentary proof between the manufacturer of a particular electromedical device and agent/representative in South Africa, in the form of signed letter authored by the international manufacturer, allowing the sale of their devices in South Africa.

### 3.3.10 Notified Body Certificate

A notified body is an organization designated by a European Member State (or by other countries under specific agreements) to assess the conformity of certain products before being placed on the market.

These bodies are entitled to carry out tasks related to conformity assessment procedures set out in the applicable legislation. Applicable legislation for manufacturers of medical devices refer to the Medical Devices Directive 93/42/EEC (MDD) as well as the Medical Device Regulation EU 2017/745 (MDR). The MDR is the successor of MDD.

### 3.3.11 Declaration of Conformity

At the end of the CE marking process the manufacturer confirms the CE marking compliance of the product by

drawing up a Declaration of Conformity (or 'DoC') and affixing the CE marking. The Declaration of Conformity is the document in which the manufacturer states that the product fulfils the essential requirements of the applicable CE marking directives or regulations.

By drawing up and signing the Declaration of Conformity, the manufacturer assumes responsibility for the compliance of the product. The Declaration of Conformity must be issued before the product is placed on the market.

The Declaration of Conformity contains all relevant compliance information. For example, the DoC indicates which EU legislation, harmonized standards and other technical specifications are complied with. The DoC contains the product specifications, the contact details of the manufacturer or his authorized representative in the European Union, and the reference to the certification body, if applicable.

### 3.3.12 South African National Clinical Trials Register

Provides the public with updated information on clinical trials on human participants being conducted in South Africa. The Register provides you with information on a trial's purpose, who can participate, where the trial is located, and contact details. Open access to information about ongoing and completed trials will satisfy the ethical duty to trial participants and will promote greater trust and public confidence in clinical research, therefore registration of clinical trials is required. https://sanctr.samrc.ac.za

### 3.3.13 Medical Ethics Committee

Ethics committees are based at clinical or academic institutions and hospitals. Ethics committee is an independent body that plays a pivotal role in ensuring that a trial is conducted in accordance with Good Clinical Practice guidelines and to safeguard the safety and well-being of subjects participating in a clinical trial. https://www.sahpra.org.za/document/sa-gcp-guidelines/ .

### 3.3.14 Research Protocol

The research protocol is a document that describes the background, rationale, objective (s), design, methodology, statistical considerations, and organization of a clinical trial. It is a document that outlines the clinical research study plan.

### 3.3.15 Informed Consent

The process of information exchange between the researcher and the human participants of research. Information provided to the human participants of research should be adequate, clearly understood by the participant of research with decision-making capacity and the research participant should voluntarily decide to participate. This entire process requires documented proof.

## 3.4 APPEAL AND LICENSE CONDITIONS

### 3.4.1 APPEAL

In terms of the hazardous substances Act when the regulator refuses to grant a license reason must be furnished to the applicants and applicant reserve right to appeal such decision. Following the unsuccessful outcome of your application, if so desired, an appeal may be lodged in terms of Section 4. subsection (6) and Section 6. of the Hazardous Substances Act. Such appeal must be in writing and forwarded to the regulator within 30 working days from date of refusal.

### 3.4.2 REPORT OF SALE (CONDITION 04)

Section 29 (1) f. of the Hazardous Substances Act, Act 15 of 1973 requires the sale of listed a Hazardous Substances to be reported. Further detail and requirements are explained in the Import License document issued once an Import License is granted as condition of the license.

### 3.4.3 ANNUAL SUBMISSION OF COMPLIANCE INFORMATION (ASOCI) (CONDITION 09)

Once an import license is issued, the license remains valid only while the EC compliance documentation is valid. An import license holder, also referred to as a Dealer, must on an annual basis, submit the following compliance information with respect to each licensed model, using form 41BM-2:

(i) Classification according to Annex IX of EC Directive 93/42/EEC

(ii) Annex(es) employed for conformity assessment

(iii) EC Certificate No(s)

(iv) Date(s) of EC Certificate(s)

(v) Expiry Date(s) of EC Certificate(s)

(vi) Notified Body Identification No

(vii) Date of EC Declaration of Conformity by the manufacturer

**Please note:**

Failure to comply will result in the cancellation of affected license holder.

### 3.4.4 Information Updates

SAHPRA must always be informed of changes to the company contact person to whom the Import License document is issued, as well as contact details and addresses.

## 4. REFERENCES

The following related documents are referenced:


4.1 South Africa, 1973. Hazardous Substances Act, 1973 (Act of 15 of 1973). https://www.sahpra.org.za/radiation-control-acts-and-regulations/

4.2 South Africa, 1973. Schedule of listed electronic products, Hazardous Substances Act, No.15 of 1973, Regulation No. R.1302. https://www.sahpra.org.za/radiation-control-acts-and-regulations/

4.3 https://www.sahpra.org.za/radiation-control-application-and-report-forms/

4.4 https://www.cipc.co.za/

4.5 https://eumdr.com/authorised-representatives

4.6 https://sanctr.samrc.ac.za

4.7 https://www.sahpra.org.za/document/sa-gcp-guidelines/ .

4.8 https://health.ec.europa.eu/medical-devices-topics-interest/notified-bodies_en

4.9 https://cemarking.net/ce-marking-knowledgebase/

4.10 https://www.sanas.co.za/


## 5. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the [Old document title if applicable here/ and old document number]. It will be reviewed on this timeframe or as and when required.