

POLICY

Requirements with regard to the application for a licence to import, manufacture or fully refurbish any listed electromedical device

Hazardous Substances Act, 1973 (Act 15 of 1973)

The primary responsibility and concern of the Directorate: Radiation Control, as part of the Department of Health, is the **safety** of the South African public, and especially the safety of the patient where listed electromedical devices are concerned. The aim of the Directorate: Radiation Control is to establish a situation where patients can have reasonable assurance that any listed electromedical device, which is used in a medical application, complies with a set of **minimum licensing requirements** with respect to safety. In terms of these licensing requirements the licence applicant is obligated to provide documentary proof that an unbroken and effective **line of communication** will be maintained at all times between the manufacturer of a particular electromedical device and the end user of that device.

The licensing requirements apply to any person or company that either

- imports any new or fully refurbished listed electromedical device; or
- manufactures any listed electromedical device in South Africa; or
- fully refurbishes any listed electromedical device in South Africa.

(i) Importation of new or fully refurbished listed electromedical devices:

- a) In the case of any new listed electromedical device, the following documentation must be submitted by the primary importer:
- Completed application form 41BM-1(IMP); **and**
 - Colour brochure (including technical specifications); **and**
 - Letter of appointment as authorised representative of the original manufacturer; **and**
 - Copy of the **EC Certificate(s) issued by a recognised Notified Body to the original manufacturer** in terms of EC Directive 93/42/EEC or 90/385/EEC (whichever one is applicable); **and**
 - Copy of the **EC Declaration of Conformity issued by the original manufacturer** in terms of EC Directive 93/42/EEC or 90/385/EEC (whichever one is applicable).

b) In the case where a pre-owned listed electromedical device has been fully refurbished overseas, the requirements for a licence to import such a device are basically the same as those for importing a new listed electromedical device. The following documentation must be submitted by the primary importer:

- Completed application form 41BM-1(IMP); **and**
- Colour brochure (including technical specifications); **and**
- Letter of appointment as authorised representative of the overseas refurbisher; **and**
- Copy of the **EC Certificate(s) issued by a recognised Notified Body to the overseas refurbisher** in terms of EC Directive 93/42/EEC or 90/385/EEC (whichever one is applicable); **and**
- Copy of the **EC Declaration of Conformity issued by the overseas refurbisher** in terms of EC Directive 93/42/EEC or 90/385/EEC (whichever one is applicable).

Please note:

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 modelname 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- & modelname. The refurbisher must give the device a completely new name that bears no resemblance to the original brand- & modelname (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.

(ii) Manufacture of listed electromedical devices in South Africa:

The following documentation must be submitted by the manufacturer in South Africa:

- Completed application form 41BM-1(MAN); **and**
- Colour brochure (including technical specifications); **and**
- Copy of the **EC Certificate(s) issued by a recognised Notified Body to the manufacturer in South Africa** in terms of EC Directive 93/42/EEC or 90/385/EEC (whichever one is applicable); **and**
- Copy of the **EC Declaration of Conformity issued by the manufacturer in South Africa** in terms of EC Directive 93/42/EEC or 90/385/EEC (whichever one is applicable).

The manufacturer of a particular electromedical device in South Africa will be permitted to manufacture but **not** distribute that device in any way until the applicable and valid EC compliance documentation (as mentioned above) has been submitted to and accepted by the Directorate: Radiation Control.

(iii) Full refurbishment of pre-owned listed electromedical devices in South Africa:

In the case where a pre-owned device is to be fully refurbished in South Africa (irrespective of whether such a device is to be imported or acquired locally), the requirements for a licence to fully refurbish are basically the same as those for manufacturing an electromedical device in South Africa. The following documentation must be submitted by the refurbisher in South Africa:

- Completed application form 41BM-1(MAN); **and**
- Colour brochure (including technical specifications); **and**
- Copy of the **EC Certificate(s) issued by a recognised Notified Body to the refurbisher in South Africa** in terms of EC Directive 93/42/EEC or 90/385/EEC (whichever one is applicable); **and**
- Copy of the **EC Declaration of Conformity issued by the refurbisher in South Africa** in terms of EC Directive 93/42/EEC or 90/385/EEC (whichever one is applicable).

The refurbisher of a particular electromedical device in South Africa will be permitted to fully refurbish such a device, which was acquired either locally or imported solely for that purpose, but may **not** distribute that device in any way until the required EC compliance documentation has been submitted to and accepted by the Directorate: Radiation Control.

(iv) Pre-owned listed electromedical devices:

The importation of any pre-owned listed electromedical device is strictly prohibited, except if such a device is to be fully refurbished in South Africa, and then the requirements as indicated in section (iii) apply.

Only electromedical devices, which had already previously been licensed either for import into or manufacture/full refurbishment in South Africa **and which had subsequently been distributed and used within South Africa**, may be resold within South Africa.