

Medical Device Regulatory Requirements for South Africa

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Introduction to South Africa Regulatory System

The medical device market is not very well regulated in South Africa. South Africa does not have a comprehensive system of medical device regulation. However, the market is very sophisticated and it is strongly advisable that the product be FDA approved or even better, carry the EC mark. The exception is for electromagnetic medical devices (or radiation emitting devices), which must be registered with the Department of Health, and must have the CE mark. FDA approved electro-medical products without the CE mark will not be accepted. A license must be obtained from the Directorate: Radiation Control, by any dealer wishing to sell a listed electro-medical product in the South African market, and the relevant application form has to be completed and attached for that purpose.

However, electro-medical devices are regulated. The Directorate: Radiation Control of the South African Department of Health is responsible for regulatory control over the sale and use of the attached schedule of listed electronic products (below).

Regulatory System

According to the Department of Health, South Africa does not make a distinction between refurbished/used and new medical equipment. Medical equipment – other than electro medical devices – including disposable or single use devices, is not regulated. The South African Department of Health is currently in the process of drafting the necessary policy documents and has indicated that these may become available some time in the future.

There are no special tariffs or restrictions reserved for used/refurbished equipment, as there is no distinction made between new and refurbished/used medical devices. No third party may legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, since each importer must obtain a license for each model that he/she imports. There are no restrictions on the number of licensed importers allowed per model currently.

The sale of used equipment locally is not regulated. Public health institutions generally do not purchase refurbished/used medical equipment due to tendering conditions and/or internal hospital policy. However, there is no law prohibiting them from doing so.

Single use or disposable devices are being reprocessed and reused by health practitioners, and is frequently done so in both private and public hospitals. Although not regulated yet, this practice is of considerable concern.

As mentioned, there are, however, exceptions with regard to specific electro medical products. Although there is no distinction between new and refurbished/used equipment, all importers – whether the product is destined for commercial or personal use – must apply for a license in terms of Section 4 (1)(b) of the Hazardous Substances Act, 1973 (Act 15 of 1973) from the Department of Health, Directorate: Radiation Control. Potential importers must apply for a license for each model and must supply the following documentation:

1. Completed application form 41BM-1, obtainable from the Radiation Directorate
2. A color brochure (including technical specifications) from the manufacturer
3. A letter of appointment as authorized representative of the original manufacturer
4. EC Certificate(s) issued by a Notified Body in terms of EC Directive 93/42/EEC, or 90/385/EEC (whichever one is applicable)
5. EC Declaration of Conformity by the manufacturer in terms of EC Directive 93/42/EEC or 90/385/EEC (whichever one is applicable).

Please note that FDA-approved only electro medical products are no longer accepted for import in South Africa. The Directorate will recognize EC certification only.

If the intention is to conduct clinical trials with a listed electro medical product, before it has been licensed to be imported or manufactured in South Africa, the importer must supply the following documentation:

1. Completed application form 41BM-1, obtainable from the Radiation Directorate
2. Color brochure (including technical specifications) from the manufacturer
3. A letter of appointment as authorized representative of the original manufacturer
4. List of medical institutions where the clinical trials will be conducted
5. List of the medical practitioners who will supervise the clinical trials
- F. 6. Copy of the letter in which the Medical Ethics Committee of a medical institution gives approval for the clinical trials to be performed at that particular medical institution

7. Copy of the approved Research Protocol for the clinical trials
8. Copy of the "Informed Consent" form

This product must be re-exported to the original manufacturer after completion of the clinical trials and may not be re-sold in South Africa. However, if the model is to be offered for local sale then EC documentation (as outlined in Points 3 and 4) must be submitted. Further, the date of importation or manufacture of units of that model may not precede the dates of the documentation required under Points 3 and 4.

Electro- medical devices are regulated. The Directorate: Radiation Control of the South African department of Health is responsible for regulatory control over the sale and use of the attached schedule of listed electronic products.

The Schedule of Listed Electronic Products Hazardous Substances Act, No. 15 of 1973 Regulation No. R. 1302, 14 June 1991 are the following:

A Any electronic product generating X-rays or other ionizing beams, electrons, neutrons or other particle radiation, namely-

1. any diagnostic X-ray unit, including medical, dental and veterinary units;
2. any therapeutic X-ray unit;
3. any X-ray unit used for industrial, research, educational, security or any other purposes;
4. any electron accelerator;
5. any heavy particle accelerator;
6. any neutron generator;
7. any electron microscope;
8. any visual display unit, including any television receiving apparatus and video display monitoring system, that employs a cathode ray tube with an accelerating voltage exceeding 15kV; and
9. any cold cathode gas discharge tube producing X-rays, including those for teaching of X-ray principles and high voltage switchgear.

B Any electronic product generating electromagnetic radiation in the ultraviolet region, namely

1. any sunlamp designed for the tanning of the skin of a human being;
2. any therapeutic lamp;
3. any high-intensity mercury-vapor discharge lamp;

4. any intra-oral curing device; and
5. any ultraviolet A lamp, including 'black lights'.

C Any electronic product emitting coherent electromagnetic radiation produced by stimulated emission, namely all laser products that emit radiation in excess of $0,8 \times 10^{-9}$ watt in the wavelength region up to and including 400 nm or that emit radiation in excess of $0,39 \times 10^{-6}$ watt in the wavelength region greater than 400 nm.

D Any electronic product emitting electromagnetic radiation in the infrared region, namely -

1. any industrial heating and drying lamp installation exceeding 200 watt; and
2. any medical heating lamp exceeding 200 watt.

E Any electronic product emitting microwaves, radio or low frequency electromagnetic radiation, namely-

1. any microwave oven;
2. any microwave diathermy unit;
3. any short-wave diathermy unit;
4. any electro surgical unit;
5. any neuro-muscular stimulator;
6. any medical magnetic stimulator;
7. any radio-frequency generating device, system or installation, including radars, generating a radio-frequency output exceeding 200 watt RMS;
8. any low power radio-frequency generating device, system or installation, including citizen band radios, land mobile transmitters, marine transmitters and two-way (walkie talkie) radios, where normal operation entails close proximity to the operator or third parties and generating a radio-frequency output exceeding 25 watt RMS;
9. any microwave generating device, system or installation, including radars, generating a microwave output exceeding 400 watt RMS ;
10. any radio-frequency sealer;
11. any magnetic resonance imaging device; and
12. any blood warmer.

F Any electronic product emitting ultrasonic vibrations, namely-

1. any diagnostic ultrasound appliance;
2. any therapeutic ultrasound appliance;
3. any surgical ultrasound appliance;
4. any lithotripsy appliance; and
5. any pest and rodent control appliance.

G Any electronic product used for medical, dental or veterinary applications employing radio-active nuclides, namely -

1. any gamma camera;
2. any whole body counter;
3. any positron emission tomography scanner;
4. any linear scanner; and
5. any single photon emission computed tomograph (SPECT).

H Any high-risk electronic product used for medical or dental applications, namely -

1. any intra-aortic balloon pump;
2. any electronically controlled ventilator;
3. any electronically controlled anesthetic machine;
4. any cardiac pacemaker;
5. any intra-cardiac electro- and phono-cardiographic monitor;
6. any electro convulsive therapy unit;
7. any photo coagulator;
8. any infusion pump;
9. any syringe pump;
10. any infant incubator;
11. any infant transport incubator;
12. any hyper baric therapy chamber;
13. any hem dialysis device;
14. any peritoneal dialysis machine;
15. any heart-lung bypass (perfusion) device;
16. any shockwave lithotripsy device;

17. any auto transfusion device;
18. any high pressure injection device;
19. any cryosurgical device; and
20. any transcutaneous O₂/CO₂ monitor.

I Any medium risk electronic product used for medical or dental applications, namely

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1. any audiometer;
2. any ambulatory electrocardiographic recorder;
3. any electrocardiograph;
4. any electroencephalograph;
5. any electromyograph;
6. any cardiac catheterization laboratory system;
7. any physiological monitor (ECG, pressure, respiration, temperature);
8. any phonocardiograph;
9. any non-invasive blood pressure monitor;
10. any cardiac output computer;
11. any plethysmograph;
12. any evoked response device;
13. any pulmonary function analyzer;
14. any blood gas analyzer;
15. any infusion controller;
16. any interferential device;
17. any capnograph; and
18. any diagnostic exercise device, including treadmill

Duties

Duties are not payable on most medical and laboratory equipment. Some, such as blood sample collection tubes may carry a Most Favored Nation (MFN) or Standard duty calculated at 10% of the value, and duties may be payable on certain plastics and disposables. An extra copy of customs paperwork will be needed for other products.

Value added tax (VAT) is payable on all items imported into South Africa. The VAT is refundable to all local VAT registered importers.

There are no special tariffs or restrictions reserved for used/refurbished equipment, as there is no distinction made between new and refurbished/used medical devices.

Procurement Practices

Generally, it is the reagents that are purchased, and the analyzers are placed with the reagents. In other words, high volume analyzers are normally rented for a minimum fee that is added to the price of the reagents. Mid-range analyzers will normally carry a small rental fee, while low-range analyzers will be purchased outright, since the small amount of reagents needed will not cover the cost of the analyzer.

In the private sector, some laboratory groups will follow a more informal tender process and procurement may also be done directly via the manufacturer if it is unavailable in the country. However, the public sector (such as the NHLS or universities and hospitals, who process their own equipment) will adopt a formal procedure and will source from local representatives only, unless the product is not available in South Africa. It is also likely that they will need to be on the institution's preferred supplier list.

All public procurements are subject to the Public Procurement Law No: 4734-4735 and the related directives, which establish the principles and procedures to be applied in procurements held by all public entities and institutions governed by public law or under public control or using public funds.

Distribution Systems

Typically, distribution is done through local agents and distributors. In South Africa, there is a distinction between an agent and a distributor. The agent orders the product on ad-hoc basis and generally works on a commission basis. The distributor will usually have a larger stocking capacity and enters into a formal agreement with the manufacturer. Some will only carry a specific brand name and become a subsidiary, e.g. Bayer (Pty) Ltd South Africa. Others may carry a string of non-competing products from different manufacturers. Most potential distributors with a national sales territory will prefer to have exclusive arrangements with the original manufacturer. It is important to ensure that local distributors have maintenance and after-sales repair capabilities, and train staff regularly.