# MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

## ACCESS to and CONTROL of MEDICAL DEVICES and IVDs

This guideline is intended to provide recommendations to Manufacturers, Importers, Exporters, Distributors, Wholesalers and Holders of Certificate of Registration (HCR) of medical devices and IVDs. It represents the Council's current thinking on the safety, quality and performance of medical devices and IVDs, access to and control of medical devices and IVDS. It is not intended as an exclusive approach. The Council reserves the right to request any additional information to establish the safety, quality and performance of a medical device or IVD 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 Council is committed to ensure that all registered medical devices and IVDs will be of the required quality, safety and performance.

Guidelines and application forms are available from the office of the Registrar and the website

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# ACCESS TO AND CONTROL OF MEDICAL DEVICES AND IVDs

## 1 INTRODUCTION

Access to medical devices and IVDs is based on the risk profile of the product to the patient and the user and public health is the key determinant regarding access to IVD medical devices and Non-IVD medical devices.

All medical devices are categorized based on the risk associated with the intended use of the medical device or IVD.

Medical devices, including in-vitro diagnostic (IVD) medical devices and non-IVD medical devices, are grouped into four classes with Class A devices presenting the lowest potential risk (e.g. a tongue depressor) and Class D devices presenting the greatest potential risk (e.g. pacemakers) to patients, users and public health.

Low to moderate, moderate to high and high risk medical devices will be assessed for safety, quality and performance during the process of conformity assessment and registration with the South African Regulatory Authority, and thereby authorized for sale in South Africa. Although Class A devices are not required to be registered, importers, manufacturers and distributors of Class A medical devices may be monitored through Medical Device Establishment Licence process.

The Regulations relating to Medical Devices and IVDs recognise four classes of medical devices and IVDs. Refer Table 1 below. This is consistent with the global approach and as recommended by the WHO.

| Class | Risk | NON –IVD Examples | IVD Examples |
|---|---|---|---|
| A | Low individual risk & minimal or no public health risk | Surgical retractors/tongue depressors | Reagents, instruments, specimen receptacle, microbiological culture medium |
| B | Low-moderate | Hypodermic needle/suction equipment | Pregnancy self-test kit, urine self-test strips to detect glucose; biochemistry tests for blood gases, hormones, vitamins |
| C | Moderate-high | Lung ventilator | Malaria rapid test; Human genetic testing, STD test; Prenatal screening tests, tumour markers, self monitoring of blood glucose |
| D | High | Heart valves/implantable defibrillator | Screening for HIV / Hepatitis B; detection of Rhesus markers; testing red blood cell antigens or antibodies within ABO blood group system |

***Table 1. Classification of Medical Devices – Non-IVDs and IVDs***

## 2 ACCESS TO AND CONTROL OF MEDICAL DEVICES AND IVDs

The following restrictions for moderate to high and high risk medical devices (including IVDs) apply

2.1 For all Class C and D medical devices intended for human use – IVDs and Non-IVDs – an order (written or oral) from a licensed health professional is required to authorise the supply or use of a Class C or a Class D medical device by a licensed retailer for use either within a health institution or by the health professional or by the patient.

2.2 For a Class D medical device – IVD or Non-IVD, because of its potentially harmful effect or the collateral measures necessary to its use, specific conditions may be required to assure safety and effectiveness; noting

a) that no condition may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Authority determines that such a restriction is required for the safe and effective use of the device as a condition of registration.

b) No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the HPCSA or the AHPCSA or has not been certified by such a Board.

c) A Class D medical device - IVD or Non-IVD - may be a “restricted medical device”.

d) The label and “Instructions for Use” (IFU) of a restricted medical device or IVD shall bear appropriate statements of the restrictions required, as the Authority may determine, as a condition of registration.

Examples of restricted devices include: –

- Analyte-Specific Reagents
- Over-the-counter (OTC) test sample collection systems for drugs of abuse testing

e) A restricted medical device will be labelled “***Restricted Use Only***” or “***For Professional Use Only***”

2.3 Most restricted devices are Class D devices; however, not all Class D devices are restricted devices.

## 3 ADVERTISING OF MEDICAL DEVICES

Regulation 21 of the Regulations relating to Medical Devices and IVDs limits the advertising of medical devices or IVDs as follows:

Regulation 21

(1) The following requirements apply to an advertisement of a medical device or IVD.

(a) Only Class A and Class B medical devices and IVDs may be advertised to the public or a lay person.

(b) despite sub-regulation (a) male or female condoms may be advertised to the public;

(c) an advertisement for a medical device or IVD may not contain a statement which deviates from, is in conflict with or goes beyond the evidence submitted in the application for registration of the medical device or IVD with regard to its safety, quality, or performance where the evidence has been

(i) accepted by the Council in respect of the medical device or IVD; and

(ii) incorporated into the approved instructions for use of the medical device or IVD.

(d) a written advertisement for a medical device or IVD must contain-

(i) the name of the medical device or IVD; and

(ii) in the case of a registered medical device or IVD, the registration number allocated to the medical device or IVD;

(e) (i) when a Class C or Class D medical device or IVD is advertised for the first time to a prospective user, written information, which must include at least the information referred to in regulation 23 or regulation 24 as the case may be, must simultaneously be given to the person to whom the oral, electronic or printed advertisement is directed, and

(ii) when the medical device or IVD is advertised on subsequent occasions, the information must be available on request.

## 4 MEDICAL DEVICES & IVDS FOR ANIMAL USE

For all Class C and D medical devices intended for animal use – IVDs and Non-IVDs – an order (written or oral) from a licensed veterinarian is required to authorise the supply or use of a Class C or a Class D medical device by a licensed retailer for use either within an animal health institution or by the veterinarian treating the animal or under the direction of the veterinarian treating the animal.

## 5 UPDATE HISTORY

| Date | Reason for update | Version & publication |
|---|---|---|
| April 2017 | First publication for comment | v1 Aug 2017 |
| 29 Sept 2017 | Due date for comment | |