MEDICINES CONTROL COUNCIL

MEDICAL DEVICE ESTABLISHMENTS: LICENCE REQUIREMENTS

To all Applicants, Manufacturers, Importers and Distributors of Medical Devices and IVDs

The Medicines Control Council (MCC) hereby advises that, in accordance with Regulation 19 of the General Regulations made in terms of Medicines and Related Substances Act, 1965 (Act no 101 of 1965), as amended-

> A person referred to in section 22C(1)(b) of the Act must apply to the Council for a licence to manufacture, import or export, act as wholesaler or distribute medicines, Scheduled substances, medical devices or IVDs.

The guideline for a licence to manufacture, import, export or distribute medical devices and IVDs, together with the application forms, are available on the MCC website: www.mccza.com

Applicants selling Medical Devices and IVDs within the borders of South Africa are encouraged to submit to the MCC an application for a licence to import, or export, or distribute, or manufacture a medical device or IVD to allow for compliance with the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

A signed, printed application with an electronic version saved on a compact disc (CD) or, alternatively, a signed, printed application submitted to the office of the Registrar of Medicines, may be followed by an application by e-mail using the following e-mail address: mdlicenceapplication@health.gov.za.
Please note that the requirements for submission on CD are detailed in the licence application forms.

DR JC GOUWS
REGISTRAR OF MEDICINES