MEDICINES CONTROL COUNCIL

POSITION STATEMENT:
CLASS A MEDICAL DEVICES

To all Applicants

The Medicines and Related Substances Act, 1965 (Act 101 of 1965) read with the General Regulations on Medical Devices, Government Gazette Notice 40480, No.1515 of 09 December 2016, provides for the regulatory oversight of Medical Devices and IVDs.

Section 22C(1)(b) of the Act requires all Medical Device establishments doing business in South Africa to obtain a licence from the MCC to manufacture, distribute and wholesale medical devices.

At the MCC meeting of 28-29 September 2017 Council resolved the following:

• Manufacturers, distributors and wholesalers of Class A medical devices, which are considered to have a measuring function or which are required to be sterile, must apply for a medical device establishment licence.

• Manufacturers, distributors and wholesalers of any other Class A medical device need not apply for a medical device establishment licence until further notice in this regard is issued, but nothing prohibits them from applying for such a licence.

DR JC GOUWS
REGISTRAR OF MEDICINES