

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