

MEDICINES CONTROL COUNCIL



TISSUE ENGINEERING PRODUCTS

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.

In accordance with the said legislation, read together with the MCC *Guideline for the Classification of Medical Devices, 8.03*, certain Tissue Engineering Products could be classified as Medical Devices as per the following Rules:

- Rule 2: Non-invasive devices intended to channel or store body liquids or tissues, liquids or gases:
Devices covered under this rule may include those that channel or store substances that will be eventually delivered into the body.
- Rule 8: Surgically invasive devices for long-term use and implantable devices:
Devices covered by this rule include implants used in orthopaedic, dental, ophthalmic and cardiovascular fields, and soft tissue implants.
- Rule 14: Devices containing animal or human cells / tissues or derivatives, or microbial or recombinant tissues, cells or substances:
This rule covers devices that contain or are made of human / animal tissues that have been rendered non-viable or derivatives from such tissues also being non-viable, or microbial or recombinant tissues, cells or substances.

These products are deemed to be sold or used in the Republic *legally*, until such time as they are called up and their legality is determined by a final decision regarding registration by the MCC, provided that, in the case of Tissue Banks and associated establishments, the sites are appropriately licensed by the National Department of Health, in terms of the provisions of Chapter 8 of the National Health Act, 2003 (Act 61 of 2003).

DR JC GOUWS
REGISTRAR OF MEDICINES
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