

CIRCULAR NO.1/2016 [REVISION 1]

REFURBISHMENT OF MEDICAL DEVICE



- New device **REGISTRATION** and shall be submitted through **MeDC@St**;
- The refurbishment activities shall be included in the scope of quality management system for the manufacture of medical device;
- Refurbishment activities shall comply with **Good Refurbishment Practice for Medical Devices (GRPMD)**;
- The medical device **shall** undergo conformity assessment by Conformity Assessment Body (CAB); and
- Provide technical details for the medical device.

- Manufacturer/ Authorised Representative (AR) shall provide **NOTIFICATION** to the Authority;
- The refurbishment activities shall be included in the scope of **quality management system** for manufacture of medical device;
- Refurbishment activities shall comply with **GRPMD**; and
- Provide technical details for the medical device.

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REFURBISHMENT OF MEDICAL DEVICE

MeDC@St v2.0
MEDICAL DEVICE CENTRALISED
ONLINE APPLICATION SYSTEM

Refurbishment activities
conducted
by third party



- Third party who wishes to carry out refurbishment activities shall obtain establishment license as **Manufacturer** and shall be responsible for **REGISTRATION** of the medical device through MeDC@St;
- Refurbishment activities shall comply with **GRPMD**;
- The medical device shall undergo conformity assessment by **CAB**; and
- Provide technical details for the medical device.