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CAB REGISTRATION NUMBER: **MDA/CAB-007**  
VALIDITY: **12/09/2020 - 11/09/2023**

### SCOPE OF REGISTRATION

| Conformity Assessment of Quality Management System (QMS) and Post-Market Surveillance System (PMSS) |           |   |
|---|-----------|---|
| 1   | ISO 13485 | Quality Management System for Medical Devices – Requirements for Regulatory Purpose |
| 2   | GDPMD     | Good Distribution Practice for Medical Devices                                      |

| Conformity Assessment of Technical Documentation |          |  |
|--|----------|--|
| 3  | MD 0101  | Non-active devices for anesthesia, emergency and intensive care      |
| 4  | MD 0102  | Non-active devices for injection, infusion, transfusion and dialysis |
| 5  | MD 0104  | Non-active medical devices with measuring function                   |
| 6  | MD 0106  | Non-active instruments   |
| 7  | MD 0108  | Non-active medical devices for disinfecting, cleaning, rinsing       |
| 8  | MD 0202  | Non-active orthopaedic implants                                      |
| 9  | MD 0301  | Bandages and wound dressings   |
| 10   | MD 0401  | Non-active dental equipment and instruments                          |
| 11   | MD 0402  | Dental materials   |
| 12   | MD 1111  | Software   |
| 13   | IVD 0201 | HIV infection (HIV 1 and 2)  |
| 14   | IVD 0202 | HTLV I and II  |
| 15   | IVD 0203 | Hepatitis B, C and D   |
| 16   | IVD 0307 | Tumoral marker: PSA  |
| 17   | IVD 0309 | Device for self-diagnosis: device for the measurement of blood sugar |
| 18   | IVD 0401 | Clinical chemistry   |
| 19   | IVD 0403 | Immunology   |
| 20   | IVD 0405 | Pregnancy and ovulation  |
| 21   | IVD 0406 | Specimen receptacles   |

| Conformity Assessment by Way of Verification |              |  |
|--|--------------|--|
| 22   | VERIFICATION | Conformity Assessment by Way of Verification |

< End of List >

**Section 10(1), Medical Device Act 2012 (Act 737) and Regulation 8, Medical Device Regulations 2012**