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CAB REGISTRATION NUMBER: **MDA/CAB-016**
 VALIDITY: **22/11/2018 - 21/11/2021**

SCOPE OF REGISTRATION

| Conformity Assessment of Quality Management System (QMS) and Post-Market Surveillance System (PMSS) | | |
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| 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 | | |
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| 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 0107 | Contraceptive medical devices |
| 8 | MD 0108 | Non-active medical devices for disinfecting, cleaning, rinsing |
| 9 | MD 0301 | Bandages and wound dressings |
| 10 | MD 0302 | Suture material and clamps |
| 11 | MD 0303 | Other medical devices for wound care |
| 12 | ***MD 1101 | Devices for extra-corporal circulation, infusion and haemopheresis |
| 13 | MD 1102 | Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia |
| 14 | MD 1103 | Devices for stimulation or inhibition |
| 15 | MD 1104 | Active surgical devices |
| 16 | MD 1106 | Active dental devices |
| 17 | MD 1107 | Active devices for disinfection and sterilization |
| 18 | MD 1109 | Active devices for patient positioning and transport |
| 19 | MD 1201 | Imaging devices utilizing ionizing radiation |
| 20 | MD 1202 | Imaging devices utilizing non-ionizing radiation |
| 21 | MD 1301 | Monitoring devices of non-vital physiological parameters |
| 22 | MD 1302 | Monitoring devices of vital physiological parameters |
| 23 | IVD 0101 | AB0 system |
| 24 | IVD 0201 | HIV infection (HIV 1 and 2) |
| 25 | IVD 0202 | HTLV I and II |
| 26 | IVD 0203 | Hepatitis B, C and D |
| 27 | IVD 0303 | Congenital infections: rubella, toxoplasmosis |
| 28 | IVD 0305 | Human infections: cytomegalovirus, chlamydia |
| 29 | IVD 0307 | Tumoral marker: PSA |
| 30 | IVD 0401 | Clinical chemistry |
| 31 | IVD 0402 | Haematology |
| 32 | IVD 0403 | Immunology |
| 33 | IVD 0404 | Molecular biology |

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| 34 | IVD 0405 | Pregnancy and ovulation |
| 35 | IVD 0406 | Specimen receptacles |
| 36 | MDS 7002 | Medical devices utilizing tissues of animal origin, including Directive 2003/32/EC |
| 37 | MDS 7206 | IVDs in sterile condition |
| 38 | MDS 7210 | IVDs utilizing material of human origin |

| Conformity Assessment by Way of Verification | | |
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| 39 | VERIFICATION | Conformity Assessment by Way of Verification |

*** means approval only for conformity assessment on infusion medical devices.

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