



ASI CERTIFICATION SDN. BHD.
 1ST FLOOR, NO. 87, JALAN NILAM 1/2
 SUBANG HI-TECH INDUSTRIAL PARK
 40000 SHAH ALAM
 SELANGOR DARUL EHSAN TEL:
+603-5621 0358
 FAX: **+603-5621 0358**

PERSON RESPONSIBLE:
MR. CHANDARASEGARAN A/L ARUMUGAM
[carumugam1952@gmail.com]

CONTACT PERSON:
MR. CHANDARASEGARAN A/L ARUMUGAM
[carumugam1952@gmail.com]

CAB REGISTRATION NUMBER: **MDA/CAB-019**
 VALIDITY: **12/11/2021 - 11/11/2024**

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 anaesthesia, emergency and intensive care |
| 4 | MD 0102 | Non-active devices for injection, infusion, transfusion and dialysis |
| 5 | MD 0103 | Non-active orthopaedic and rehabilitation devices |
| 6 | MD 0104 | Non-active medical devices with measuring function |
| 7 | MD 0106 | Non-active instruments |
| 8 | MD 0301 | Bandages and wound dressings |
| 9 | MD 1101 | Devices for extra-corporal circulation, infusion and haemopheresis |
| 10 | MD 1102 | Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia |
| 11 | MD 1103 | Devices for stimulation or inhibition |
| 12 | MD 1104 | Active surgical devices |
| 13 | MD 1105 | Active ophthalmologic devices |
| 14 | MD 1106 | Active dental devices |
| 15 | MD 1107 | Active devices for disinfection and sterilization |
| 16 | MD 1108 | Active rehabilitation devices and active prostheses |
| 17 | MD 1109 | Active devices for patient positioning and transport |
| 18 | MD 1201 | Imaging devices utilizing ionizing radiation |
| 19 | MD 1202 | Imaging devices utilizing non-ionizing radiation |
| 20 | MD 1302 | Monitoring devices of vital physiological parameters |
| 21 | MD 1401 | Devices utilising ionizing radiation |
| 22 | MD 1402 | Devices utilising non-ionizing radiation |
| 23 | MD 1403 | Devices for hyperthermia / hypothermia |
| 24 | MDS 7004 | Medical devices referencing the Directive 2006/42/EC on machinery |
| 25 | MDS 7005 | Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE) |

| Conformity Assessment by Way of Verification | | |
|--|--------------|--|
| 26 | 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

MDA Website: www.mda.gov.my • Email Address: cab.registration@mdb.gov.my