Reference Number: **(38) MDA.600-1/1/18 JILID 3**
Revision Date: **JULY 1, 2020**

**ASI CERTIFICATION SDN. BHD.**
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CAB REGISTRATION NUMBER: **MDA/CAB-019**
VALIDITY: **08/11/2018 – 07/11/2021**

**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 0104 | Non-active medical devices with measuring function |
| 4 | MD 0106 | Non-active instruments |
| 5 | MD 1101 | Devices for extra-corporal circulation, infusion and haemopheresis |
| 6 | MD 1102 | Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia |
| 7 | MD 1103 | Devices for stimulation or inhibition |
| 8 | MD 1104 | Active surgical devices |
| 9 | MD 1105 | Active ophthalmologic devices |
| 10 | MD 1106 | Active dental devices |
| 11 | MD 1107 | Active devices for disinfection and sterilization |
| 12 | MD 1108 | Active rehabilitation devices and active prostheses |
| 13 | MD 1109 | Active devices for patient positioning and transport |
| 14 | MD 1201 | Imaging devices utilizing ionizing radiation |
| 15 | MD 1202 | Imaging devices utilizing non-ionizing radiation |
| 16 | MD 1301 | Monitoring devices of non-vital physiological parameters |
| 17 | MDS 7004 | Medical devices referencing the Directive 2006/42/EC on machinery |
| 18 | MDS 7005 | Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE) |

| **Conformity Assessment by Way of Verification** | | |
|---|---|---|
| 19 | 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**