



MEDIVICE CERTIFICATION SDN. BHD.

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CAB REGISTRATION NUMBER: MDA/CAB-020
VALIDITY: 04/04/2022 - 03/04/2025

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 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 0107	Contraceptive medical devices
9	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
10	MD 0109	Non-active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
11	MD 0301	Bandages and wound dressings
12	MD 0302	Suture material and clamps
14	MD 0303	Other medical devices for wound care
15	MD 0401	Non-active dental equipment and instruments
16	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
17	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
18	MD 1103	Devices for stimulation or inhibition
19	MD 1104	Active surgical devices
20	MD 1106	Active dental devices
21	MD 1108	Active rehabilitation devices and active prostheses
22	MD 1109	Active devices for patient positioning and transport
23	MD 1301	Monitoring devices of non-vital physiological parameters
24	MD 1302	Monitoring devices of vital physiological parameters
25	MD 1403	Devices for hyperthermia / hypothermia
26	MD 1404	Devices for (extracorporeal) shock-wave therapy (lithotripsy)
27	IVD 0305	Human infections: cytomegalovirus, chlamydia
28	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
29	IVD 0401	Clinical chemistry
30	IVD 0403	Immunology
31	IVD 0404	Molecular biology
32	IVD 0405	Pregnancy and ovulation
33	IVD 0406	Specimen receptacles

34	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment
35	MDS 7206	IVDs in sterile condition
36	MDS 7210	IVDs utilizing material of human origin
Conformity Assessment by Way of Verification		
37	VERIFICATION	Conformity Assessment by Way of Verification

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

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