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VALIDITY: **14/04/2020 – 13/04/2023**

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 0103	Non-active orthopaedic and rehabilitation devices
4	MD 0104	Non-active medical devices with measuring function
5	MD 0106	Non-active instruments
6	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
7	MD 0401	Non-active dental equipment and instruments
8	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
9	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
10	MD 1103	Devices for stimulation or inhibition
11	MD 1104	Active surgical devices
12	MD 1106	Active dental devices
13	MD 1108	Active rehabilitation devices and active prostheses
14	MD 1109	Active devices for patient positioning and transport
15	MD 1301	Monitoring devices of non-vital physiological parameters
16	MD 1302	Monitoring devices of vital physiological parameters
17	MD 1403	Devices for hyperthermia / hypothermia
18	MD 1404	Devices for (extracorporeal) shock-wave therapy (lithotripsy)
19	IVD 0101	AB0 system
20	IVD 0102	Rhesus (C, c, D, E, e)
21	IVD 0103	Anti-Kell
22	IVD 0201	HIV infection (HIV 1 and 2)
23	IVD 0203	Hepatitis B, C and D
24	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
25	IVD 0401	Clinical chemistry
26	IVD 0403	Immunology
27	IVD 0404	Molecular biology
28	IVD 0405	Pregnancy and ovulation
29	IVD 0406	Specimen receptacles

Conformity Assessment by Way of Verification		
30	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