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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 0108	Non-active medical devices for disinfecting, cleaning, rinsing
9	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
10	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
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	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
25	IVD 0404	Molecular biology
26	IVD 0406	Specimen receptacles
27	MDS 7004	Medical devices referencing the Directive 2006/42/EC on machinery
28	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)
29	MDS 7206	IVDs in sterile condition
30	MDS 7210	IVDs utilizing material of human origin

Conformity Assessment by Way of Verification		
31	VERIFICATION	Conformity Assessment by Way of Verification

< End of List >

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