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CAB REGISTRATION NUMBER: **MDA/CAB-016**
VALIDITY: **22/11/2018 – 21/11/2021**

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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0104	Non-active medical devices with measuring function
6	MD 0106	Non-active instruments
7	MD 0107	Contraceptive medical devices
8	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
9	MD 0301	Bandages and wound dressings
10	MD 0302	Suture material and clamps
11	MD 0303	Other medical devices for wound care
12	***MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
13	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
14	MD 1103	Devices for stimulation or inhibition
15	MD 1104	Active surgical devices
16	MD 1106	Active dental devices
17	MD 1107	Active devices for disinfection and sterilization
18	MD 1109	Active devices for patient positioning and transport
19	MD 1201	Imaging devices utilizing ionizing radiation
20	MD 1202	Imaging devices utilizing non-ionizing radiation
21	MD 1301	Monitoring devices of non-vital physiological parameters
22	MD 1302	Monitoring devices of vital physiological parameters
23	IVD 0101	AB0 system
24	IVD 0201	HIV infection (HIV 1 and 2)
25	IVD 0202	HTLV I and II
26	IVD 0203	Hepatitis B, C and D
27	IVD 0303	Congenital infections: rubella, toxoplasmosis
28	IVD 0305	Human infections: cytomegalovirus, chlamydia
29	IVD 0307	Tumoral marker: PSA
30	IVD 0401	Clinical chemistry
31	IVD 0402	Haematology
32	IVD 0403	Immunology
33	IVD 0404	Molecular biology

34	IVD 0405	Pregnancy and ovulation
35	IVD 0406	Specimen receptacles
36	MDS 7002	Medical devices utilizing tissues of animal origin, including Directive 2003/32/EC
37	MDS 7206	IVDs in sterile condition
38	MDS 7210	IVDs utilizing material of human origin

Conformity Assessment by Way of Verification		
39	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