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CAB REGISTRATION NUMBER: **MDA/CAB-005**
VALIDITY: **21/11/2019 – 20/11/2022**

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 0201	Non-active cardiovascular implants
9	MD 0202	Non-active orthopaedic implants
10	MD 0203	Non-active functional implants
11	MD 0204	Non-active soft tissue implants
12	MD 0401	Non-active dental equipment and instruments
13	MD 0402	Dental materials
14	MD 0403	Dental implants
15	IVD 0201	HIV infection (HIV 1 and 2)
16	IVD 0202	HTLV I and II
17	IVD 0203	Hepatitis B, C and D
18	IVD 0305	Human infections: cytomegalovirus, chlamydia
19	IVD 0306	HLA tissue groups: DR, A, B
20	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
21	IVD 0403	Immunology
22	MDS 7206	IVDs in sterile condition
23	MDS 7210	IVDs utilizing material of human origin

Conformity Assessment by Way of Verification		
24	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