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CAB REGISTRATION NUMBER: **MDA/CAB-022**
VALIDITY: **17/06/2021-16/06/2024**

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 0108	Non-Active Medical Devices for Disinfecting, Cleaning, Rinsing
6	MD 0301	Bandages and Wound Dressings
7	MD 1102	Respiratory Devices, Including Hyperbaric Chambers for Oxygen Therapy, Inhalation Anaesthesia
8	MD 1103	Devices for Stimulation or Inhibition
9	MD 1108	Active Rehabilitation Devices and Active Prostheses
10	MD 1109	Active Devices for Patient Positioning and Transport
11	MD 1402	Devices Utilising Non-Ionizing Radiation
12	IVD 0101	AB0 System
13	IVD 0102	Rhesus (C, C, D, E, E)
14	IVD 0103	Anti-Kell
15	IVD 0201	HIV Infection (HIV 1 And 2)
16	IVD 0203	Hepatitis B, C And D
17	IVD 0301	Anti-Duffy And Anti-Kidd
18	IVD 0305	Human Infections: Cytomegalovirus, Chlamydia
19	IVD 0307	Tumoral Marker: PSA
20	IVD 0309	Devices for Self-Diagnosis: Device for The Measurement of Blood Sugar
21	IVD 0401	Clinical Chemistry
22	IVD 0402	Haematology
23	IVD 0403	Immunology
24	IVD 0406	Specimen Receptacles

Conformity Assessment by Way of Verification		
25	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