



LIST OF REGISTERED CONFORMITY ASSESSMENT BODY

Section 10 (1) Medical Device Act 2012 (Act 737)
Regulation 8, Medical Device Regulations 2012 (MDR 2012)

CAB REGISTRATION NUMBER: **MDA/CAB-022**
VALIDITY: **17/06/2024 - 16/06/2027**

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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 0103	Non-Active Orthopaedic And Rehabilitation Devices
4	MD 0104	Non-Active Medical Devices with Measuring Function
5	MD 0105	Non-active ophthalmologic devices
6	MD 0106	Non-active instruments
7	MD 0108	Non-Active Medical Devices for Disinfecting, Cleaning, Rinsing
8	MD 0301	Bandages and Wound Dressings
9	MD 0303	Other medical devices for wound care
10	MD 1102	Respiratory Devices, Including Hyperbaric Chambers for Oxygen Therapy, Inhalation Anaesthesia
11	MD 1103	Devices for Stimulation or Inhibition
12	MD 1105	Active ophthalmologic devices
13	MD 1107	Active devices for disinfection and sterilisation
14	MD 1108	Active Rehabilitation Devices and Active Prostheses
15	MD 1109	Active Devices for Patient Positioning and Transport
16	MD 1402	Devices Utilising Non-Ionizing Radiation
17	IVD 0101	ABO System
18	IVD 0102	Rhesus (C, C, D, E, E)
19	IVD 0103	Anti-Kell
20	IVD 0201	HIV Infection (HIV 1 And 2)
21	IVD 0202	HTLV I and II
22	IVD 0203	Hepatitis B, C And D
23	IVD 0301	Anti-Duffy And Anti-Kidd
24	IVD 0302	Irregular anti-erythrocyte antibodies
25	IVD 0303	Congenital infections: rubella, toxoplasmosis
26	IVD 0305	Human Infections: Cytomegalovirus, Chlamydia

27	IVD 0306	HLA tissue groups: DR, A, B
28	IVD 0307	Tumoral Marker: PSA
29	IVD 0309	Devices for Self-Diagnosis: Device for The Measurement of Blood Sugar
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 7004	Medical devices referencing the Directive 2006/42/EC on machinery
37	MDS 7206	IVDs in sterile condition
38	MDS 7207	IVDs utilizing micromechanics

Conformity Assessment by Way of Verification		
39	VERIFICATION	Conformity Assessment by Way of Verification

< End of List >

Note: **Blue**-in-colour font means 'new updated information'.

**Section 10(1), Medical Device Act 2012 (Act 737)
Regulation 8, Medical Device Regulations 2012**

For more enquiries, please contact us:

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