

CAB REGISTRATION NUMBER: **MDA/CAB-025**
VALIDITY: **18/10/2023 - 17/10/2026**



LEADER CERTIFICATION SDN. BHD.

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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 orthopedic and rehabilitation devices
4	MD 0106	Non-active instruments
5	MD 0202	Non-active orthopedic implants
6	MD 0203	Non-active functional implants

Conformity Assessment by Way of Verification		
7	VERIFICATION	Conformity Assessment by Way of Verification

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