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CAB REGISTRATION NUMBER: **MDA/CAB-013**
 VALIDITY: **27/09/2018 - 26/09/2021**

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 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 0401	Non-active dental equipment and instruments
9	IVD 0403	Immunology
10	IVD 0404	Molecular biology
11	IVD 0406	Specimen receptacles
12	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification

13	VERIFICATION	Conformity Assessment by Way of Verification
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Section 10(1), Medical Device Act 2012 (Act 737) and Regulation 8, Medical Device Regulations 2012