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Validity MDA/CAB-015: 27/02/2019 – 26/02/2022

SCOPE OF REGISTRATION

Conformity Assessment of Quality Management System (QMS)

(1)	GDPMD	Good Distribution Practice for Medical Devices
(2)	ISO 13485	Quality Management Systems for Medical Devices – Requirements for Regulatory Purpose

Conformity Assessment of Medical Device Technical Areas

(3)	MD 0106	Non-active instruments
(4)	MD 0301	Bandages and wound dressings

Conformity Assessment of Medical Device Technical Areas

(5)	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 Regulation 2012