



**KIWA INTERNATIONAL CERTIFICATIONS SDN. BHD.**

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CAB REGISTRATION NUMBER: **MDA/CAB-021**  
VALIDITY: : **04/04/2019 – 03/04/2022**

#### 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 0102	Non-active devices for injection, infusion, transfusion and dialysis
4	MD 0103	Non-active orthopaedic and rehabilitation devices
5	MD 0106	Non-active instruments
6	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
7	MD 0202	Non-active orthopaedic implants
8	MD 0301	Bandages and wound dressings
9	MD 0303	Other medical devices for wound care
10	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
11	MD 1107	Active devices for disinfection and sterilization

Conformity Assessment by Way of Verification		
12	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**