



KIWA INTERNATIONAL CERTIFICATIONS SDN. BHD.

2A JALAN ASTANA 1D
BANDAR BUKIT RAJA 41050
KLANG
SELANGOR DARUL EHSAN
TEL: **+603-3359 7583**
FAX: **+603-3359 6583**

PERSON RESPONSIBLE:
DR. KENNY CHAN TEIK KEN
[kenny@kiwacert.com]

CONTACT PERSON:
MS. IRMALISA BINTI SAMSURI
[kiwa.auditing@gmail.com]

CAB REGISTRATION NUMBER: **MDA/CAB-021**
VALIDITY: **04/04/2022 - 03/04/2025**

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
5	MD 0104	Non-active medical devices with measuring function
6	MD 0106	Non-active instruments
8	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
9	MD 0301	Bandages and wound dressings
10	MD 0303	Other medical devices for wound care
11	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
12	MD 1107	Active devices for disinfection and sterilization

Conformity Assessment by Way of Verification		
13	VERIFICATION	Conformity Assessment by Way of Verification

< End of List >

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