



Tel: (+603) 8230 0398/0356

Portal: www.mda.gov.my

Email: cabregistration@mda.gov.my



BSI SERVICES MALAYSIA SDN. BHD.
SUITE 29.01 LEVEL 29,
THE GARDENS NORTH TOWER,
MID VALLEY CITY, LINGKARAN SYED PUTRA,
59200 KUALA LUMPUR, MALAYSIA
TEL: +603 – 9212 9638 FAX: +603 – 9212 9639

Person Responsible:-

MR. POON CHEONG YUEN

[CheongYuen.Poon@bsigroup.com]

Contact Person:-

MR. AZRULAZWAR BIN WAN AZIZAN

[azrul.wanazizan@bsigroup.com]

Validity **MDA/CAB-005: 21/11/2019 - 20/11/2022**

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 0101	Non-active devices for anesthesia, emergency and intensive care
(4)	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
(5)	MD 0103	Non-active orthopedic and rehabilitation devices
(6)	MD 0104	Non-active medical devices with measuring function
(7)	MD 0106	Non-active instruments
(8)	MD 0201	Non-active cardiovascular implants
(9)	MD 0202	Non-active orthopedic implants
(10)	MD 0203	Non-active functional implants
(11)	MD 0204	Non-active soft tissue implants
(12)	MD 0401	Non-active dental equipment and instruments
(13)	MD 0402	Dental materials
(14)	MD 0403	Dental implants
(15)	IVD 0201	HIV infection (HIV 1 and 2)
(16)	IVD 0202	HTLV I and II
(17)	IVD 0203	Hepatitis B, C and D
(18)	IVD 0305	Human infections: cytomegalovirus, chlamydia
(19)	IVD 0306	HLA tissue groups: DR, A, B
(20)	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
(21)	IVD 0403	Immunology
(22)	MDS 7206	IVDs in sterile condition
(23)	MDS 7210	IVDs utilizing material of human origin

Conformity Assessment of Medical Device Technical Areas

(24)	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