Medical Device AUTHORITY MALAYSIA

Tel: (+603) 8230 0332/0356
Portal: www.mda.gov.my
Email: cabregistration@mda.gov.my

BSI SERVICES MALAYSIA SDN. BHD.
UNIT 10-03, TOWER A, NO.8, JLN KERINCHI
THE VERTICAL BUSINESS SUITES
BANGSAR SOUTH, 59200 KUALA LUMPUR,
TEL: +603 – 2242 4211 FAX: +603 – 2242 4218

Person Responsible:-
MS. EVELYN CHYE POH YIN
[evelyn.chye@bsigroup.com]

Contact Person:-
MS. EVELYN CHYE POH YIN
[evelyn.chye@bsigroup.com]

Validity **MDA/CAB-005**: **21/11/2016 - 20/11/2019**

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)	MD 1104	Active surgical devices
(16)	MD 1301	Monitoring devices of non-vital physiological parameters
(17)	IVD 0101	AB0 system
(18)	IVD 0102	Rhesus (C, c, D, E, e)
(19)	IVD 0103	Anti-Kell
(20)	IVD 0201	HIV infection (HIV 1 and 2)
(21)	IVD 0202	HTLV I and II
(22)	IVD 0203	Hepatitis B, C and D
(23)	IVD 0303	Congenital infections: rubella, toxoplasmosis
(24)	IVD 0304	Hereditary disease: phenylketonuria
(25)	IVD 0305	Human infections: cytomegalovirus, chlamydia
(26)	IVD 0306	HLA tissue groups: DR, A, B
(27)	IVD 0307	Tumoral marker: PSA
(28)	IVD 0308	Risk of trisomy 21 (incl. software)
(29)	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
(30)	IVD 0401	Clinical chemistry
(31)	IVD 0403	Immunology
(32)	IVD 0404	Molecular biology
(33)	IVD 0405	Pregnancy and ovulation
(34)	IVD 0406	Specimen receptacles
(35)	MDS 7206	IVDs in sterile condition
(36)	MDS 7210	IVDs utilizing material of human origin
Conformity Assessment of Medical Device Technical Areas		
(37)	VERIFICATION	Conformity Assessment by Way of Verification