

(1) Medical Devices, Non-Active		(3) Active Implantable medical devices	
	MD 0100 - General non-active, non-implantable medical devices		AIMD 0100 – General active implantable medical devices
	MD 0101 - Non-active devices for anaesthesia, emergency and intensive care		AIMD 0101 - Active implantable medical device for stimulation / inhibition
	MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis		AIMD 0102 - Active implantable medical device delivering drugs or other substances
	MD 0103 - Non-active orthopaedic and rehabilitation devices		AIMD 0103 - Active implantable medical devices substituting or replacing organ functions
	MD 0104 - Non-active medical devices with measuring function	(4) In Vitro Diagnostic (IVD) Medical Device	
	MD 0105 - Non-active ophthalmologic devices		IVD 0100 - List A Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups
	MD 0106 - Non-active instruments		IVD 0101 - ABO System
	MD 0107 - Contraceptive medical devices		IVD 0102 - Rhesus (C,c,D,E,e)
	MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing		IVD 0103 - Anti-Kell
	MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)		IVD 0200 – List A Reagents and Reagent Product, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of marker
	MD 0200 - Non-active implants		IVD 0201 - HIV Infection
	MD 0201 - Non-active cardiovascular implants		IVD 0202 - HTLV I and II
	MD 0202 - Non-active orthopaedic implants		IVD 0203 - Hepatitis B, C and D
	MD 0203 - Non-active functional implants		IVD 0300 – List B Reagents, Reagent Products and device for self – Diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating
	MD 0204 - Non-active soft tissue implants		IVD 0301 Anti-Duffy and anti-Kidd
	MD 0300 - Devices for wound care		IVD 0302 - Irregular anti-erythrocytic antibodies
	MD 0301 - Bandages and wound dressings		IVD 0303 - Congenital infections: rubella, toxoplasmosis
	MD 0302 - Suture material and clamps		IVD 0304 - Hereditary disease: phenylketonuria
	MD 0303 - Other medical devices for wound care		IVD 0305 - Human infections: cytomegalovirus, chlamydia
	MD 0400 - Non-active dental devices and accessories		IVD 0306 - HLA tissue groups: DR, A, B
	MD 0401 - Non-active dental equipment and instruments		IVD 0307 - Tumoral marker: PSA
	MD 0402 - Dental materials		IVD 0308 - Risk of trisomy 21
	MD 0403 - Dental implants		IVD 0309 - Device for self-diagnosis: device for measurement of blood sugar
(2) Medical Devices, Non-Active			IVD 0400 – Device for Self-Testing
	MD 1100 - General active medical devices		IVD 0401 - Clinical chemistries
	MD 1101 - Devices for extra-corporal circulation, infusion and thermophoresis		IVD 0402 - Haematology
	MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation Anaesthesia,		IVD 0403 - Immunology
	MD 1103 - Devices for stimulation or inhibition		IVD 0404 - Molecular biology
	MD 1104 - Active surgical devices		IVD 0405 - Pregnancy and ovulation
	MD 1105 - Active ophthalmologic devices		IVD 0406 - Specimen receptacles
	MD 1106 - Active dental devices	(5) Specifics of medical devices and active medical devices	
	MD 1107 - Active devices for disinfection and sterilisation		MDS 7001 - Medical devices incorporating medicinal substances, according to directive 2001/83/EC
	MD 1108 - Active rehabilitation devices and active prostheses		MDS 7002 - Medical devices utilising tissues of animal origin, including Directive 2003/32/EC
	MD 1109 - Active devices for patient positioning and transport		MDS 7003 - Medical devices incorporation derivatives of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC
	MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)		MDS 7004 - Medical devices referencing Directive 2006/42/EC on machinery
	MD 1111 - Software		MDS 7005 - Medical devices referencing the directive 89/686/EEC on personal protective equipment (PPE)
	MD 1200 – Device for imaging	(6) Specifics of In-Vitro Diagnostic (IVD) Medical Devices	
	MD 1201 - Imaging devices utilising ionizing radiation		MDS 7200 – IVD Specifics
	MD 1202 - Imaging devices utilising non-ionizing radiation		MDS 7206 – IVDs in sterile condition
	MD 1301 - Monitoring devices of non-vital physiological parameters		MDS 7207 – IVDs utilising micromechanics
	MD 1302 - Monitoring devices of vital physiological parameters		MDS 7208 – IVDs utilising nanomaterials
	MD 1401 - Devices utilising ionizing radiation		MDS 7209 - IVDs utilising biological active coating and/ or material
	MD 1402 - Devices utilising non-ionizing radiation		MDS 7210 - IVDs utilising of human origin
	MD 1403 - Devices for hyperthermia / hypothermia		
	MD 1404 - Devices for (extracorporeal) shock-wave therapy (lithotripsy)		



GENUINE DIAMOND SDN BHD

No. 43B, Jalan BP 7/12,
Bandar Bukit Puchong, 47120
Puchong, Selangor Darul Ehsan, Malaysia.
TEL: 03-8069 1111/ 1114 /1118 FAX: 03-8069 1133

CODE SCOPE EXPRESSION

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 anaesthesia, emergency and intensive care
4.	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
7.	MD 0107	Contraceptive medical devices
8.	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
9.	MD 0301	Bandages and wound dressings
10.	MD 0302	Suture material and clamps
11.	MD 0303	Other medical devices for wound care
12.	MD 1101	Devices for extra-corporal circulation, infusion and thermophoresis
13.	MD 1103	Devices for stimulation or inhibition
14.	MD 1104	Active surgical devices
15.	MD 1105	Active ophthalmologic devices
16.	MD 1106	Active dental devices
17.	MD 1107	Active devices for disinfection and sterilisation
18.	MD 1109	Active devices for patient positioning and transport
19.	MD 1201	Imaging devices utilizing ionizing radiation
20.	MD 1202	Imaging devices utilizing non-ionizing radiation
21.	MD 1301	Monitoring devices of non-vital physiological parameters
22.	MD 1302	Monitoring devices of vital physiological parameters
23.	IVD 0101	ABO system
24.	IVD 0201	HIV Infection (HIV 1 and 2) D



GENUINE DIAMOND SDN BHD

No. 43B, Jalan BP 7/12,
Bandar Bukit Puchong, 47120
Puchong, Selangor Darul Ehsan, Malaysia.
TEL: 03-8069 1111/ 1114 /1118 FAX: 03-8069 1133

	CODE	SCOPE EXPRESSION
25.	IVD 0202	HTLV I and II
26.	IVD 0203	Hepatitis B, C and D
27.	IVD 0303	Congenital infections: rubella, toxoplasmosis
28.	IVD 0305	Human infections: cytomegalovirus, chlamydia
29.	IVD 0307	Tumoral marker: PSA
30.	IVD 0401	Clinical chemistry
31.	IVD 0402	Haematology
32.	IVD 0403	Immunology
33.	IVD 0404	Molecular biology
34.	IVD 0405	Pregnancy and ovulation
35.	IVD 0406	Specimen receptacles
36.	MDS 7002	Medical Devices utilising tissues of animal origin, including Directive 2003/32/EC
37.	MDS 7206	IVD's in sterile condition
38.	MDS 7210	IVD's utilising material of human origin
Conformity Assessment of Medical Device Technical Areas		
39.	VERIFICATION	Conformity Assessment by Way of Verification