



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)



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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