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SCOPE OF REGISTRATION

Conformity Assessment of Quality Management System (QMS)

(1)	GDPMD	Good Distribution Practice for Medical Devices
(2)	ISO 13485	Quality Management System 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 orthopaedic and rehabilitation devices
(6)	MD 0104	Non-active medical devices with measuring function
(7)	MD 0105	Non-active ophthalmologic devices
(8)	MD 0106	Non-active instruments
(9)	MD 0107	Contraceptive medical devices
(10)	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
(11)	MD 0109	Non-active devices for in vitro fertilisation (IVF) & assisted reproductive technologies (ART)
(12)	MD 0201	Non-active cardiovascular implants
(13)	MD 0202	Non-active orthopaedic implants
(14)	MD 0203	Non-active functional implants
(15)	MD 0204	Non-active soft tissue implants
(16)	MD 0301	Bandages and wound dressings
(17)	MD 0302	Suture material and clamps
(18)	MD 0303	Other medical devices for wound care
(19)	MD 0401	Non-active dental equipment and instruments
(20)	MD 0402	Dental materials
(21)	MD 0403	Dental implants
(22)	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
(23)	MD 1106	Active dental devices
(24)	MD 1108	Active rehabilitation devices and active prostheses
(25)	MD 1109	Active devices for patient positioning and transport
(26)	MD 1110	Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
(27)	MD 1301	Monitoring devices of non-vital physiological parameters
(28)	MD 1403	Devices for hyperthermia / hypothermia
(29)	IVD 0101	ABO system
(30)	IVD 0102	Rhesus (C, c, D, E, e)
(31)	IVD 0103	Anti-Kell
(32)	IVD 0201	HIV infection (HIV 1 and 2)
(33)	IVD 0203	Hepatitis B, C and D
(34)	IVD 0305	Human infections: cytomegalovirus, chlamydia
(35)	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
(36)	IVD 0401	Clinical chemistry
(37)	IVD 0403	Immunology
(38)	IVD 0404	Molecular biology
(39)	IVD 0405	Pregnancy and ovulation
(40)	IVD 0406	Specimen receptacles
(41)	MDS 7001	Medical devices incorporating medicinal substances, according to Directive 2001/83/EC
(42)	MDS 7206	IVDs in sterile condition
(43)	MDS 7210	IVDs utilizing material of human origin

Conformity Assessment of Medical Device Technical Areas

(44)	VERIFICATION	Conformity Assessment by Way of Verification
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