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Accreditation Certificate

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Type of Laboratory	Testing Laboratory
Name of Laboratory	Fukushima Medical Device Industry Promotion Agency Division of Safety and Biological Compability Assessment Electrical and physico-chemical Testing Department
Address	Fukushima Medical Device Development Support Center,27-8,Mansuida,Tomitamachi,Koriyama-shi, Fukushima,Japan

1) Premises on which testing activities are performed

Name of Premises	Fukushima Medical Device Industry Promotion Agency Division of Safety and Biological Compability Assessment Electrical and physico-chemical Testing Department	
Address of Premises	Postal code	963-8041
	Address	Fukushima Medical Device Development Support Center, 27-8,Mansuida,Tomitamachi,Koriyama-shi, Fukushima
Testing service at permanent facilities or on site testing service	<input checked="" type="checkbox"/> Testing service at permanent facilities <input type="checkbox"/> On site testing service	

Scope of Accreditation

FIELD	M21 Electrical Testing
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CODE OF CLASSIFICATION, NAME	TEST METHOD STANDARD
M21.36 Medical Electrical Devices	IEC 60601-1(except relevant electrical component test standards) 4, 5, 6, 7, 8.1~8.9(except 8.8.4.2, 8.9.3) , 9.3, 9.4, 9.6.2(except 9.6.2.2), 11.1, 11.6.5(except IP1X~IP6X), 11.8, 13.2.7, 13.2.8, 15(except 15.5) JIS T 0601-1 (except relevant electrical component test standards) 4, 5, 6, 7, 8.1~8.9(except 8.8.4.2, 8.9.3) , 9.3, 9.4, 9.6.2(except 9.6.2.2), 11.1, 11.6.5(except IP1X~IP6X), 11.8, 13.2.7, 13.2.8, 15(except 15.5)
M21.4 Electromagnetic compatibility testing M21.4.1 Continuous conducted disturbances tests	IEC 60601-1-2 JIS T 0601-1-2 CISPR 11 (except 6.4, 10, Annex H) CISPR 32 VCCI-CISPR 32
M21.4 Electromagnetic compatibility testing M21.4.4 Conducted emission tests at telecommunication ports	CISPR 32 (except A11.2, A11.3 in Table A.11) (except A12.2, A12.3 in Table A.12) (except Table A.13) VCCI-CISPR 32 (except A11.2, A11.3 in Table A.11) (except A12.2, A12.3 in Table A.12) (except Table A.13)



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Address	Fukushima Medical Device Development Support Center,27-8,Mansuida,Tomitamachi,Koriyama-shi, Fukushima,Japan

CODE OF CLASSIFICATION, NAME	TEST METHOD STANDARD
M21.4 Electromagnetic compatibility testing M21.4.6 Electric field test(30MHz to 1GHz)	IEC 60601-1-2 JIS T 0601-1-2 CISPR 11 (except 6.4, 10, Annex H) CISPR 32 VCCI-CISPR 32
M21.4 Electromagnetic compatibility testing M21.4.7 Electric field test(1GHz and over)	IEC 60601-1-2 JIS T 0601-1-2 CISPR 11 (except 6.4, 10, Annex H) CISPR 32 VCCI-CISPR 32
M21.4 Electromagnetic compatibility testing M21.4.10 Harmonic current emission tests	IEC 60601-1-2 JIS T 0601-1-2 IEC 61000-3-2
M21.4 Electromagnetic compatibility testing M21.4.12 Voltage fluctuation and flicker tests	IEC 60601-1-2 JIS T 0601-1-2 IEC 61000-3-3
M21.4 Electromagnetic compatibility testing M21.4.14 Electrostatic discharge immunity tests	IEC 60601-1-2 JIS T 0601-1-2 IEC 61000-4-2 JIS C 61000-4-2
M21.4 Electromagnetic compatibility testing M21.4.15 RF radiated electromagnetic field immunity tests	IEC 60601-1-2 JIS T 0601-1-2 IEC 61000-4-3 JIS C 61000-4-3
M21.4 Electromagnetic compatibility testing M21.4.16 Electrical fast transient / burst tests	IEC 60601-1-2 JIS T 0601-1-2 IEC 61000-4-4 JIS C 61000-4-4
M21.4 Electromagnetic compatibility testing M21.4.17 Surge immunity tests	IEC 60601-1-2 JIS T 0601-1-2 IEC 61000-4-5 (Except 6.3.3) JIS C 61000-4-5 (Except 6.3.3)
M21.4 Electromagnetic compatibility testing M21.4.18 RF conducted immunity tests	IEC 60601-1-2 JIS T 0601-1-2 IEC 61000-4-6 JIS C 61000-4-6

Accreditation No.	RTL04460
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Address	Fukushima Medical Device Development Support Center,27-8,Mansuida,Tomitamachi,Koriyama-shi, Fukushima,Japan

CODE OF CLASSIFICATION, NAME	TEST METHOD STANDARD
M21.4 Electromagnetic compatibility testing	IEC 60601-1-2 JIS T 0601-1-2
M21.4.19 Power frequency magnetic field immunity tests	IEC 61000-4-8 JIS C 61000-4-8
M21.4 Electromagnetic compatibility testing	IEC 60601-1-2 JIS T 0601-1-2
M21.4.20 A.C. power supply fluctuation immunity tests	IEC 61000-4-11 (Except 3 phase) JIS C 61000-4-11 (Except 3 phase)
M21.5 Environmental testing	IEC 60529 (Except IP1X-IP6X, IPX9)
M21.5.16 Water tests	JIS C 0920 (Except IP1X-IP6X)

Accreditation No.	RTL04460
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Scope of Accreditation

FIELD	M26 Chemical Testing
CODE OF CIT*1	M26.A8
NAME OF CIT	Resin, rubber, Related product

CODE & NAME OF TCT*2	PROPERTIES MEASURED	TEST METHOD STANDARD / STANDARD OPERATING PROCEDURE
B3.6 Mass spectrometry I : GC/MS	50 mg/kg \leq PBDEs \leq 2000 mg/kg 50 mg/kg \leq PBBs \leq 2000 mg/kg	IEC 62321-6
	50 mg/kg \leq DIBP, DBP, BBP, DEHP \leq 100000 mg/kg	IEC 62321-8
B3.7 Mass spectrometry II : ICP-MS	5 mg/kg \leq Pb, Cd, Cr \leq 2500 mg/kg	IEC 62321-5
	10 mg/kg \leq Hg \leq 2500 mg/kg	IEC 62321-4 Ed.1.1
B3.1 X - ray fluorescence spectrometry analysis : XRF	Pb \geq 100mg/kg Cd \geq 100mg/kg Hg \geq 100mg/kg Cr \geq 100mg/kg Br \geq 100mg/kg	IEC 62321-3-1

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