



JAB



Accreditation Certificate

Appendix

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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	

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) 4.11, 5.7, 5.9, 8.4.3, 8.6.4, 8.7, 8.8.3, 8.8(except 8.8.4.2), 8.9(except 8.9.3), 9.3, 9.4(except 9.4.4), 9.6.2(except 9.6.2.2), 11.1, 15.3(except 15.3.3), 15.4.7 JIS T 0601-1:2012+amd1(except relevant electrical component test standards) 4.11, 5.7, 5.9, 8.4.3, 8.6.4, 8.7, 8.8.3, 8.8(except 8.8.4.2), 8.9(except 8.9.3), 9.3, 9.4(except 9.4.4), 9.6.2(except 9.6.2.2), 11.1, 15.3(except 15.3.3), 15.4.7
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
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
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
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

Accreditation No.

RTL04460

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

Scope of Accreditation

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

*1 CIT: Classification of Item to be Tested

*2 TCT: Technical Classification of Test

CODE & NAME OF TCT*2	PROPERTIES MEASURED	TEST METHOD STANDARD / STANDARD OPERATING PROCEDURE
B3.6 Mass spectrometry I : GC/MS	10 mg/kg \leq PBDEs \leq 2000 mg/kg	IEC 62321-6
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
B3.1 X - ray fluorescence spectrometry analysis : XRF	Pb, Cd, Hg, Cr, Br	IEC 62321-3-1

Japan Accreditation Board