



Accreditation No.

RTL04460

Accreditation Certificate

Appendix

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Type of Laboratory	Testing
Name of Laboratory	Fukushima Medical Device Industry Promotion Agency Electrical, Physical & Analysis Test Group Safety Evaluation Department
Address	Fukushima Medical Device Development Support Centre 27-8, Mansuida, Tomitamachi, Koriyama-shi Fukushima 963-8041, Japan

1) Premises on which testing activities are performed

Name of Premises	Fukushima Medical Device Industry Promotion Agency Electrical, Physical & Analysis Test Group Safety Evaluation Department
Address	Fukushima Medical Device Development Support Centre 27-8, Mansuida, Tomitamachi, Koriyama-shi Fukushima 963-8041, Japan
Testing service at permanent facilities or on site testing service	☒ Testing service at permanent facilities ☐ 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 60601-1:2005 + A1:2012 (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, 12.3, 13.2.7, 13.2.8, 15 (except 15.5) IEC 60601-1:2005 + A1:2012 + A2:2020 (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, 12.3, 13.2.7, 13.2.8, 15 (except 15.5) IEC 60601-1-8:2006 + A1:2012 IEC 60601-1-8:2006 + A1:2012 + A2:2020 4, 5, 6.3 JIS T 0601-1 :2017(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, 12.3, 13.2.7, 13.2.8, 15 (except 15.5) JIS T 0601-1 :2023(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, 12.3, 13.2.7, 13.2.8, 15 (except 15.5) JIS T 60601-1-8:2012 JIS T 60601-1-8:2023 4, 5, 6.3



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CODE OF CLASSIFICATION, NAME	TEST METHOD STANDARD
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 IEC 61326-1, JIS C 61326-1 IEC 61326-2-6, JIS C 61326-2-6
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)
M21.4 Electromagnetic compatibility testing M21.4.6 Electric field test (30 MHz to 1 GHz)	IEC 60601-1-2, JIS T 0601-1-2 CISPR 11 (except 6.4, 10, Annex H) CISPR 32, VCCI-CISPR 32 IEC 61326-1, JIS C 61326-1 IEC 61326-2-6, JIS C 61326-2-6
M21.4 Electromagnetic compatibility testing M21.4.7 Electric field test (1 GHz 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 IEC 61326-1, JIS C 61326-1 IEC 61326-2-6, JIS C 61326-2-6
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 IEC 61326-1 IEC 61326-2-6
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 IEC 61326-1, JIS C 61326-1 IEC 61326-2-6, JIS C 61326-2-6
M21.4 Electromagnetic compatibility testing M21.4.15 RF radiated electromagnetic field immunity tests	IEC 60601-1-2 (except 8.11), JIS T 0601-1-2 IEC 61000-4-3, JIS C 61000-4-3 IEC 61326-1, JIS C 61326-1 IEC 61326-2-6, JIS C 61326-2-6
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 IEC 61326-1, JIS C 61326-1 IEC 61326-2-6, JIS C 61326-2-6



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CODE OF CLASSIFICATION, NAME	TEST METHOD STANDARD
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) IEC 61326-1, JIS C 61326-1 IEC 61326-2-6, JIS C 61326-2-6
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 IEC 61326-1, JIS C 61326-1 IEC 61326-2-6, JIS C 61326-2-6
M21.4 Electromagnetic compatibility testing M21.4.19 Power frequency magnetic field immunity tests	IEC 60601-1-2, JIS T 0601-1-2 IEC 61000-4-8, JIS C 61000-4-8 IEC 61326-1, JIS C 61326-1 IEC 61326-2-6, JIS C 61326-2-6
M21.4 Electromagnetic compatibility testing M21.4.20 A.C. power supply fluctuation immunity tests	IEC 60601-1-2, JIS T 0601-1-2 IEC 61000-4-11, JIS C 61000-4-11 IEC 61326-1, JIS C 61326-1 IEC 61326-2-6, JIS C 61326-2-6
M21.4 Electromagnetic compatibility testing M21.4.30 Radiated fields in close proximity immunity tests	IEC 60601-1-2, JIS T 0601-1-2 IEC 61000-4-39 (below 26 MHz)
M21.5 Environmental testing M21.5.16 Water tests	IEC 60529 (except IP1X~IP6X, IPX9) JIS C 0920 (except IP1X~IP6X)

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
B2.1 Absorption spectrometry : Ultraviolet - visible spectrometry	Cr(VI) Measurement Range 10 mg/kg or more, 2500 mg/kg or less	IEC 62321-7-2



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

(Notes on Accreditation Certificate)

The laboratory is only accredited for laboratory activities outlined within the methods listed above. Reference to any other activity within these standards, such as risk management or risk assessment, does not fall within the laboratory's accredited capabilities.

When version information of standards or methods are not identified in the scope, laboratories shall adapt to use the current version of such standards within six months at latest from the issued date of current version.

Notes for EMC test laboratory for FCC

Accreditation does not imply acceptance to the FCC equipment authorization program. Please see the FCC website (<https://apps.fcc.gov/oetcf/eas/>) for a listing of FCC approved laboratories.

Japan Accreditation Board