



Accreditation No.

RTL04460

# Accreditation Certificate

## Appendix

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Type of Laboratory	Testing Laboratory
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 of Premises	Postal code	963-8041
	Address	Fukushima Medical Device Development Support Centre 27-8, Mansuida, Tomitamachi, Koriyama-shi, Fukushima, Japan
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 60601-1:2005 + 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,



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CODE OF CLASSIFICATION, NAME	TEST METHOD STANDARD
	15 (except 15.5) JIS T 60601-1-8:2012 JIS T 60601-1-8:2023 4, 5, 6.3
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



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CODE OF CLASSIFICATION, NAME	TEST METHOD STANDARD
M21.4 Electromagnetic compatibility testing	IEC 60601-1-2, JIS T 0601-1-2
M21.4.16 Electrical fast transient / burst tests	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
M21.4 Electromagnetic compatibility testing	IEC 60601-1-2, JIS T 0601-1-2
M21.4.17 Surge immunity tests	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	IEC 60601-1-2, JIS T 0601-1-2
M21.4.18 RF conducted immunity tests	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	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 IEC 61326-1, JIS C 61326-1 IEC 61326-2-6, JIS C 61326-2-6
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, 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	IEC 60601-1-2, JIS T 0601-1-2
M21.4.30 Radiated fields in close proximity immunity tests	IEC 61000-4-39 (below 26 MHz)
M21.5 Environmental testing	IEC 60529 (except IP1X~IP6X, IPX9)
M21.5.16 Water tests	JIS C 0920 (except IP1X~IP6X)



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## 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	10 mg/kg $\leq$ Cr(VI) $\leq$ 2500 mg/kg	IEC 62321-7-2
B3.6 Mass spectrometry I : GC/MS	10 mg/kg $\leq$ PBDEs $\leq$ 2000 mg/kg 10 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, Cr $\leq$ 2500 mg/kg 2 mg/kg $\leq$ Cd $\leq$ 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 $\geq$ 100 mg/kg Cd $\geq$ 100 mg/kg Hg $\geq$ 100 mg/kg Cr $\geq$ 100 mg/kg Br $\geq$ 100 mg/kg	IEC 62321-3-1

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