



Accreditation No.

RTL04460

# Accreditation Certificate

## Appendix

(Page 1/3)

|                    |                                                                                                                                  |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Type of Laboratory | Testing Laboratory                                                                                                               |
| Name of Laboratory | Fukushima Medical Device Industry Promotion Agency<br>Electrical, Physical & Analysis Test Group<br>Safety Evaluation Department |
| Address            | Fukushima Medical Device Development Support Centre<br>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<br>Electrical, Physical & Analysis Test Group<br>Safety Evaluation Department |                                                                                                                                 |
| Address of Premises                                                | Postal code                                                                                                                      | 963-8041                                                                                                                        |
|                                                                    | Address                                                                                                                          | Fukushima Medical Device Development Support Centre<br>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<br><input type="checkbox"/> On site testing service |

### Scope of Accreditation

|       |                        |
|-------|------------------------|
| FIELD | M21 Electrical Testing |
|-------|------------------------|

| CODE OF CLASSIFICATION, NAME                                                                               | TEST METHOD STANDARD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| M21.36<br>Medical Electrical Devices                                                                       | IEC 60601-1:2005 + A1:2012 (except relevant electrical component test standards)<br>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)<br>IEC 60601-1-8:2006 + A1:2012<br>JIS T 0601-1 (except relevant electrical component test standards)<br>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)<br>JIS T 60601-1-8 |
| M21.4 Electromagnetic compatibility testing<br>M21.4.1 Continuous conducted disturbances tests             | IEC 60601-1-2, JIS T 0601-1-2<br>CISPR 11 (except 6.4, 10, Annex H)<br>CISPR 32, VCCI-CISPR 32<br>IEC 61326-1, JIS C 61326-1<br>IEC 61326-2-6, JIS C 61326-2-6                                                                                                                                                                                                                                                                                                                                                                            |
| M21.4 Electromagnetic compatibility testing<br>M21.4.4 Conducted emission tests at telecommunication ports | CISPR 32<br>(except A11.2, A11.3 in Table A.11)<br>(except A12.2, A12.3 in Table A.12)<br>(except Table A.13)<br>VCCI-CISPR 32<br>(except A11.2, A11.3 in Table A.11)<br>(except A12.2, A12.3 in Table A.12)<br>(except Table A.13)                                                                                                                                                                                                                                                                                                       |





Accreditation No.

RTL04460

# Accreditation Certificate

## Appendix

(Page 2/3)

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

| CODE OF CLASSIFICATION,<br>NAME                                                                          | TEST METHOD STANDARD                                                                                                                                            |
|----------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| M21.4 Electromagnetic compatibility testing<br>M21.4.6 Electric field test (30 MHz to 1 GHz)             | IEC 60601-1-2, JIS T 0601-1-2<br>CISPR 11 (except 6.4, 10, Annex H)<br>CISPR 32, VCCI-CISPR 32<br>IEC 61326-1, JIS C 61326-1<br>IEC 61326-2-6, JIS C 61326-2-6  |
| M21.4 Electromagnetic compatibility testing<br>M21.4.7 Electric field test (1 GHz and over)              | IEC 60601-1-2, JIS T 0601-1-2<br>CISPR 11 (except 6.4, 10, Annex H)<br>CISPR 32, VCCI-CISPR 32                                                                  |
| M21.4 Electromagnetic compatibility testing<br>M21.4.10 Harmonic current emission tests                  | IEC 60601-1-2, JIS T 0601-1-2<br>IEC 61000-3-2<br>IEC 61326-1, JIS C 61326-1<br>IEC 61326-2-6, JIS C 61326-2-6                                                  |
| M21.4 Electromagnetic compatibility testing<br>M21.4.12 Voltage fluctuation and flicker tests            | IEC 60601-1-2, JIS T 0601-1-2<br>IEC 61000-3-3<br>IEC 61326-1<br>IEC 61326-2-6                                                                                  |
| M21.4 Electromagnetic compatibility testing<br>M21.4.14 Electrostatic discharge immunity tests           | IEC 60601-1-2, JIS T 0601-1-2<br>IEC 61000-4-2, JIS C 61000-4-2<br>IEC 61326-1, JIS C 61326-1<br>IEC 61326-2-6, JIS C 61326-2-6                                 |
| M21.4 Electromagnetic compatibility testing<br>M21.4.15 RF radiated electromagnetic field immunity tests | IEC 60601-1-2 (except 8.11),<br>JIS T 0601-1-2<br>IEC 61000-4-3, JIS C 61000-4-3<br>IEC 61326-1, JIS C 61326-1<br>IEC 61326-2-6, JIS C 61326-2-6                |
| M21.4 Electromagnetic compatibility testing<br>M21.4.16 Electrical fast transient / burst tests          | IEC 60601-1-2, JIS T 0601-1-2<br>IEC 61000-4-4, JIS C 61000-4-4<br>IEC 61326-1, JIS C 61326-1<br>IEC 61326-2-6, JIS C 61326-2-6                                 |
| M21.4 Electromagnetic compatibility testing<br>M21.4.17 Surge immunity tests                             | IEC 60601-1-2, JIS T 0601-1-2<br>IEC 61000-4-5 (except 6.3.3)<br>JIS C 61000-4-5 (except 6.3.3)<br>IEC 61326-1, JIS C 61326-1<br>IEC 61326-2-6, JIS C 61326-2-6 |
| M21.4 Electromagnetic compatibility testing<br>M21.4.18 RF conducted immunity tests                      | IEC 60601-1-2, JIS T 0601-1-2<br>IEC 61000-4-6, JIS C 61000-4-6<br>IEC 61326-1, JIS C 61326-1<br>IEC 61326-2-6, JIS C 61326-2-6                                 |
| M21.4 Electromagnetic compatibility testing<br>M21.4.19 Power frequency magnetic field immunity tests    | IEC 60601-1-2, JIS T 0601-1-2<br>IEC 61000-4-8, JIS C 61000-4-8<br>IEC 61326-1, JIS C 61326-1<br>IEC 61326-2-6, JIS C 61326-2-6                                 |





Accreditation No.

RTL04460

# Accreditation Certificate

## Appendix

(Page 3/3)

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

| CODE OF CLASSIFICATION,<br>NAME                          | TEST METHOD STANDARD                                                                             |
|----------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| M21.4 Electromagnetic<br>compatibility testing           | IEC 60601-1-2, JIS T 0601-1-2                                                                    |
| M21.4.20 A.C. power supply<br>fluctuation immunity tests | IEC 61000-4-11, JIS C 61000-4-11<br>IEC 61326-1, JIS C 61326-1<br>IEC 61326-2-6, JIS C 61326-2-6 |
| M21.5 Environmental testing                              | IEC 60529 (except IP1X~IP6X, IPX9)                                                               |
| M21.5.16 Water tests                                     | 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<br>TCT*2                                                    | PROPERTIES<br>MEASURED                                                                                                                                 | TEST METHOD STANDARD /<br>STANDARD OPERATING PROCEDURE |
|----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| B2.1 Absorption<br>spectrometry :<br>Ultraviolet - visible<br>spectrometry | 10 mg/kg $\leq$ Cr(VI)<br>$\leq$ 2500 mg/kg                                                                                                            | IEC 62321-7-2                                          |
| B3.6 Mass spectrometry<br>I :<br>GC/MS                                     | 10 mg/kg $\leq$ PBDEs<br>$\leq$ 2000 mg/kg<br>10 mg/kg $\leq$ PBBs<br>$\leq$ 2000 mg/kg<br>50 mg/kg $\leq$ DIBP, DBP, BBP,<br>DEHP $\leq$ 100000 mg/kg | IEC 62321-6<br>IEC 62321-8                             |
| B3.7 Mass spectrometry<br>II :<br>ICP-MS                                   | 5 mg/kg $\leq$ Pb, Cr $\leq$ 2500<br>mg/kg<br>2 mg/kg $\leq$ Cd $\leq$ 2500 mg/kg<br>10 mg/kg $\leq$ Hg $\leq$ 2500 mg/kg                              | IEC 62321-5<br>IEC 62321-4 Ed.1.1                      |
| B3.1 X-ray<br>fluorescence<br>spectrometry analysis :<br>XRF               | Pb $\geq$ 100 mg/kg<br>Cd $\geq$ 100 mg/kg<br>Hg $\geq$ 100 mg/kg<br>Cr $\geq$ 100 mg/kg<br>Br $\geq$ 100 mg/kg                                        | IEC 62321-3-1                                          |

# Japan Accreditation Board