# Declaration of Conformity

We, Fukuda Denshi Co., Ltd., hereby issue this European Declaration of Conformity under our sole responsibility that the following medical device is in conformity with the relevant provisions of the European regulations and directives as follows.

| **Manufacturer** | |
|---|---|
| Name of Company | Fukuda Denshi Co., Ltd. |
| Address | 3-39-4 Hongo, Bunkyo-ku, Tokyo 113-8483 Japan |
| SRN | JP-MF-000008253 |
| Location of Design | Fukuda Denshi Co., Ltd.<br>2-35-8 Hongo, Bunkyo-ku, Tokyo 113-8420 Japan |
| Location of Design | Fukuda Denshi Co., Ltd.<br>2-35-27 Hongo, Bunkyo-ku, Tokyo 113-8420 Japan |
| Location of Production | Fukuda Denshi Co., Ltd. Shiroi Factory<br>305-1 Naka, Shiroi-shi, Chiba 270-1495 Japan |

| **Medical Device** | | |
|---|---|---|
| Product Category | Measuring and Monitoring Device for Vital Signs | |
| Device Name | ECG & Respiration Transmitter model LX-8100 type LX-8100<br>*Refer to the Appendix 1 for details. | ☒ MDR ((EU)2017/745)<br>☒ RoHS Directive (2011/65/EU)<br>☒ RE Directive (2014/53/EU) |
| | Reusable Accessories for LX-8100<br>*Refer to the Appendix 2 for details. | ☒ MDR ((EU)2017/745)<br>☒ RoHS Directive (2011/65/EU)<br>☐ RE Directive (2014/53/EU) |
| | Disposable Accessories for LX-8100<br>*Refer to the Appendix 3 for details. | ☒ MDR ((EU)2017/745)<br>☒ RoHS Directive (2011/65/EU)<br>☐ RE Directive (2014/53/EU) |

| **Notified Body** | |
|---|---|
| Name of Company | BSI Group The Netherlands B.V. |
| Address | Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands |
| NB Number | 2797 |
| Certificate No. | MDR 743406 |
| Conformity Assessment Procedure | Medical Devices Regulation (EU) 2017/745, Annex IX Chapter I and III<br>Note: BSI's CE Certificate covers only Medical Devices Regulation (EU) 2017/745 Class IIa and IIb, but not RoHS Directive 2011/65/EU & RE Directive (2014/53/EU) |

| **Authorized Representative (MDR & RoHS)** | |
|---|---|
| Name of Company | Emergo Europe |
| Address | Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands |
| SRN | NL-AR-000000116 |

Date of issue : 30 August 2024
Place of issue : Tokyo, Japan
Edition : 3rd
First issued : 2 September 2022

M. Onda

Makoto ONDA
PRRC, Senior Manager
Quality Assurance Headquarters

**Appendix 1**

| **Medical Device description** | |
|---|---|
| Device Name | ECG & Respiration Transmitter model LX-8100 type LX-8100 |
| GMDN / EMDN Code | GMDN<br>33586 (General-purpose multi-parameter bedside monitor)<br>EMDN<br>Z12050803 (ELECTROCARDIOGRAPH TELEMETRY SYSTEM TRANSMITTERS) |
| Intended Purpose | This device intends to continuously transmit the vital signs to a specified monitor by wireless network. The measurable vital signs are electrocardiogram and respiration waveform. |
| Device Class | Class IIb |
| Device Classification Rule | Rule 10<br>Annex VIII of Medical Devices Regulation (EU) 2017/745 |
| EEE Categories | 8 (Annex I of RoHS Directive 2011/65/EU) |
| RE Directive | Annex II of Directive 2014/53/EU |
| Technical Document | MDR / RoHS: 063020H-20727<br>RED: 063020D-17C04 |
| Basic UDI-DI | 4538612022009X |

Details of the system components:

| No. | Device Name | Model | Type |
|---|---|---|---|
| 1. | ECG & Respiration Transmitter model LX-8100 type LX-8100 | LX-8100 | LX-8100 |

**Appendix 2**

| **Medical Device description** | |
|---|---|
| Device Name | Reusable Accessories for LX-8100 |
| Intended Purpose | These are accessories to support LX-8100 or use to operate LX-8100.<br><br>LX-8100 intends to continuously transmit the vital signs to a specified monitor by wireless network. The measurable vital signs are electrocardiogram and respiration waveform. |
| Device Class | Class I (self-certified) |
| Device Classification Rule | Rule 1<br>Annex VIII of Medical Devices Regulation (EU) 2017/745 |
| EEE Categories | 8 (Annex I of RoHS Directive 2011/65/EU) |
| RE Directive | N/A |
| Technical Document | MDR / RoHS: 063020H-20727<br>RED: N/A |
| Basic UDI-DI | 4538612022019Z |

Reusable Accessories for LX-8100 intended to be used in combination with ECG & Respiration Transmitter model LX-8100 type LX-8100.

| No. | Device Name | Model | Type |
|---|---|---|---|
| 1. | Neck Strap | OAT-03A | - |

**Appendix 3**

| Medical Device description | |
|---|---|
| Device Name | Disposable Accessories for LX-8100 |
| Intended Purpose | These are accessories to support LX-8100 or use to operate LX-8100.<br><br>LX-8100 intends to continuously transmit the vital signs to a specified monitor by wireless network. The measurable vital signs are electrocardiogram and respiration waveform. |
| Device Class | Class I (self-certified) |
| Device Classification Rule | Rule 1<br>Annex VIII of Medical Devices Regulation (EU) 2017/745 |
| EEE Categories | 8 (Annex I of RoHS Directive 2011/65/EU) |
| RE Directive | N/A |
| Technical Document | MDR / RoHS: 063020H-20727<br>RED: N/A |
| Basic UDI-DI | 4538612022019Z |

Disposable Accessories for LX-8100 intended to be used in combination with ECG & Respiration Transmitter model LX-8100 type LX-8100.

| No. | Device Name | Model | Type |
|---|---|---|---|
| 1. | Disposable Case (For LX-8100) | ABT-810D | - |