
Declaration of Conformity

We declare under our sole responsibility that the following product to which this declaration relates is in conformity with the standards or other normative documents under the provisions of Medical Devices Regulation (EU) 2017/745 and RoHS Directive 2011/65/EU.

Product Category: Measuring and Monitoring Equipment for Vital Signs
Device Name: ECG & Respiration Transmitter model LX-8100 type LX-8100
Model: LX-8100
Type: LX-8100
Classification: Class IIb
Rule 10, Annex VIII of Medical Devices Regulation (EU) 2017/745
Basic UDI-DI: 4538612022009X
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.
EEE Categories: 8
Annex I of RoHS Directive 2011/65/EU
Manufacturer: Fukuda Denshi Co., Ltd.
3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
SRN: JP-MF-000008253
European Authorized Representative: Emergo Europe
Prinsessegracht 20, 2514 AP The Hague, The Netherlands
SRN: NL-AR-000000116
Applied Annex: Annex IX of Medical Devices Regulation (EU) 2017/745
Notified Body: BSI Group The Netherlands B.V. (2797)
Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Certificate No.: MDR 743406
Note: BSI's CE Certificate covers only Medical Devices Regulation (EU) 2017/745 Class IIa and IIb, but not RoHS Directive 2011/65/EU.
Technical Documents: No. 063020H-20727

We declare under our sole responsibility that the following product to which this declaration relates is in conformity with the standards or other normative documents under the provisions of RE Directive 2014/53/EU.

Product Category: Measuring and Monitoring Equipment for Vital Signs
Device Name: ECG & Respiration Transmitter model LX-8100 type LX-8100
Model: LX-8100
Type: LX-8100
Manufacturer: Fukuda Denshi Co., Ltd.
3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
Location of design: Fukuda Denshi Co., Ltd. Hongo Office
2-35-8 Hongo, Bunkyo-ku, Tokyo, Japan
Location of production: Fukuda Denshi Co., Ltd. Shiroy Factory
305-1 Naka, Shiroy-shi, Chiba, Japan
Applied Annex: Annex II of Directive 2014/53/EU
Technical file: No. 063020D-17C04

Date of issue : 2 September 2022
Place of issue : Tokyo, Japan
Edition : 1st
First issued : 2 September 2022



Takashi Nomura
General Manager
Quality Assurance Department
