

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 Directive 93/42/EEC and RoHS Directive 2011/65/EU.

Common name: **ECG & Respiration Transmitter**
 Model name: **LX-8100**
 Classification: **Class II b** (according to Annex IX of Directive 93/42/EEC)
 Categories: **8** (according to Annex I of Directive 2011/65/EU)
 Accessories: See Appendix 1
 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. Shiroi Factory**
 305-1 Naka, Shiroi-shi, Chiba, Japan

Applied Annex: **Annex II** of Directive 93/42/EEC
 (Accessories: Annex VII of Directive 93/42/EEC)
 Notified Body: **British Standards Institution (0086)**
 Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP
 United Kingdom
 Certificate No.: **CE 01612**

Note: BSI's CE Certificate covers only MDD 93/42/EEC Class IIa and IIb, but not RoHS Directive 2011/65/EU and Class I accessories.

Technical file: No. 063020D-17C01, 1st edition

Date of issue : 1 March 2018
 Edition : 1st
 First issued : 1 March 2018



Takashi Nomura
 General Manager
 Quality Assurance Department

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Applied Annex: **Annex II** of Directive 2014/53/EU

Technical file: No. 063020D-17C04, 1st edition

Date of issue : 1 March 2018
Edition : 1st
First issued : 1 March 2018


Takashi Nomura
General Manager
Quality Assurance Department

Appendix 1 (List of Accessories)

Standard Accessories

Common name	Model
Neck Strap	OAT-3A
ECG Hook Type Lead Cable	CMT-02HTH-0.8DU
Operation Manual	4L011496*
Disposable Portable Case	ABT-810D

** means revision number

Related Products

Common name	Model
ECG Hook Type Lead Cable	CMT-01HTH-0.8DU
ECG Hook Type Lead Cable	CMT-02HTH-0.8DU
ECG Hook Type Lead Cable	CMT-03HTH-0.8DU
ECG Clip Type Lead Cable	CMT-01CTH-0.8DU
ECG Clip Type Lead Cable	CMT-02CTH-0.8DU
ECG Clip Type Lead Cable	CMT-03CTH-0.8DU

