

## 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 Rule 10, Annex IX of Directive 93/42/EEC)
Categories:	8 (according to Annex I of Directive 2011/65/EU)
Manufacturer:	<b>Fukuda Denshi Co., Ltd.</b> 3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
European Authorized Representative:	<b>Emergo Europe</b> Prinsessegracht 20, 2514 AP The Hague, The Netherlands
Applied Annex:	Annex II (excluding section 4) of Directive 93/42/EEC
Notified Body:	<b>BSI Group The Netherlands B.V. (2797)</b> Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Certificate No.:	<b>CE 01612</b> <b>Note:</b> 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.
Accessories:	See Appendix 1
Classification:	Class I (according to Rule 1, Annex IX of Directive 93/42/EEC)
Categories:	8 (according to Annex I of Directive 2011/65/EU)
Manufacturer:	<b>Fukuda Denshi Co., Ltd.</b> 3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
European Authorized Representative:	<b>Emergo Europe</b> Prinsessegracht 20, 2514 AP The Hague, The Netherlands
Applied Annex:	Annex VII of Directive 93/42/EEC
Technical file:	No. 063020D-17C01, 2nd edition

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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.

Common name: **ECG & Respiration Transmitter**  
Model name: **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, 2nd edition**

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**Appendix 1 (List of Accessories)**

Common name	Model
Neck Strap	OAT-03A
Disposable Portable Case	ABT-810D