

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: TM XMTR Module
Model name: HLX-801
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: Fukuda Denshi Co., Ltd.
3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
European Authorized Representative: Emergo Europe
Prinsessegracht 20, 2514 AP The Hague, The Netherlands
Applied Annex: Annex VII of Directive 93/42/EEC

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: Fukuda Denshi Co., Ltd.
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Applied Annex: Annex VII of Directive 93/42/EEC

Technical file: No. 063020D-12607, 7th edition

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: **TM XMTR Module**
Model name: **HLX-801**

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-17614, 1st edition

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Following products are in conformity with the provisions of Medical Devices Directive 93/42/EEC and RoHS Directive 2011/65/EU starting with the below mentioned S/N.

Model	S/N
HLX-801	50300111 ~

Appendix 1 (List of Accessories)

Common name	Model
HLX-801 mounting bracket	OAT-8185A
HLX-801 cover (DSL-8001)	OAT-01A
