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:	Electrocardiograph
Device Name:	CardiMax FX-8300
Model:	FX-8300
Type:	FX-8300
Classification:	Class IIa
	Rule 10, Annex VIII of Medical Devices Regulation (EU) 2017/745
Basic UDI-DI:	4538612010009E
Intended Purpose:	This device is intended to be used for the electrocardiogram examination for diagnosis or group health checkup of the cardiovascular system. It is neither for home-use nor for monitoring of the cardiovascular system. It intends to help doctor to make the diagnosis and does not intend to make the diagnosis solely by itself.
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 Chapter I and III 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.
Accessories:	See Appendix 1
Technical Documents:	No. 064080D-22103

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:	Electrocardiograph
Device Name:	CardiMax FX-8300
Model:	FX-8300
Type:	FX-8300
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 2014/53/EU
Technical file:	064080H-18B05

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Place of issue : Tokyo, Japan
Edition : 1st
First issued : 30 November 2022

Takashi Nomura
General Manager
Quality Assurance Department

Appendix 1 (List of Accessories)

Device Name	Type
ECG INTERPRETATION SOFTWARE	FP-810