

Declaration of Conformity

We, Fukuda Denshi Co., Ltd., hereby issue this European Declaration of Conformity under our sole responsibility that the following medical device is in conformity with the relevant provisions of the European regulations and directives as follows.


Manufacturer	
Name of Company	Fukuda Denshi Co., Ltd.
Address	3-39-4 Hongo, Bunkyo-ku, Tokyo 113-8483 Japan
SRN	JP-MF-000008253
Location of Design	Fukuda Denshi Co., Ltd. 2-35-8 Hongo, Bunkyo-ku, Tokyo 113-8420 Japan
Location of Design	Fukuda Denshi Co., Ltd. 2-35-27 Hongo, Bunkyo-ku, Tokyo 113-8420 Japan
Location of Production	Fukuda Denshi Co., Ltd. Shiroy Factory 305-1 Naka, Shiroy-shi, Chiba 270-1495 Japan

Medical Device		
Product Category	Electrocardiograph	
Device Name	CardiMax FX-8300 *Refer to the Appendix 1 for details.	<input checked="" type="checkbox"/> MDR ((EU)2017/745) <input checked="" type="checkbox"/> RoHS Directive (2011/65/EU) <input checked="" type="checkbox"/> RE Directive (2014/53/EU)
	Reusable Accessories for FX-8300 *Refer to the Appendix 2 for details.	<input checked="" type="checkbox"/> MDR ((EU)2017/745) <input checked="" type="checkbox"/> RoHS Directive (2011/65/EU) <input type="checkbox"/> RE Directive (2014/53/EU)

Notified Body	
Name of Company	BSI Group The Netherlands B.V.
Address	Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
NB Number	2797
Certificate No.	MDR 743406
Conformity Assessment Procedure	Medical Devices Regulation (EU) 2017/745, Annex IX Chapter I and III Note: BSI's CE Certificate covers only Medical Devices Regulation (EU) 2017/745 Class IIa and IIb, but not RoHS Directive 2011/65/EU & RE Directive (2014/53/EU)

Authorized Representative (MDR & RoHS)	
Name of Company	Emergo Europe
Address	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
SRN	NL-AR-000000116

Date of issue : 28 July 2023
 Place of issue : Tokyo, Japan
 Edition : 2nd
 First issued : 30 November 2022


 Takashi Nomura
 General Manager
 Quality Assurance Department

Appendix 1

Medical Device description	
Device Name	CardiMax FX-8300
GMDN / EMDN Code	GMDN 16231 (Electrocardiograph, professional, multichannel) EMDN Z12050301 (GENERAL PURPOSE ELECTROCARDIOGRAPHS)
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.
Device Class	Class IIa
Device Classification Rule	Rule 10 Annex VIII of Medical Devices Regulation (EU) 2017/745
EEE Categories	8 (Annex I of RoHS Directive 2011/65/EU)
RE Directive	Annex II of Directive 2014/53/EU
Technical Document	MDR / RoHS: 064080D-22103 RED: 064080H-18B05
Basic UDI-DI	4538612010009E

Details of the system components:

No.	Device Name	Model	Type
1	CardiMax FX-8300	FX-8300	-

List of Accessories for Class IIa medical device:

No.	Device Name	Model	Type
1	ECG INTERPRETATION SOFTWARE	FP-810	-

Appendix 2

Medical Device description	
Device Name	Reusable Accessories for FX-8300
EMDN Code	Z12050301 (GENERAL PURPOSE ELECTROCARDIOGRAPHS)
Intended Purpose	<p>These are accessories to support FX-8300 or use to operate FX-8300.</p> <p>FX-8300 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.</p>
Device Class	Class I (self-certified)
Device Classification Rule	Rule 1 Annex VIII of Medical Devices Regulation (EU) 2017/745
EEE Categories	8 (Annex I of RoHS Directive 2011/65/EU)
RE Directive	N/A
Technical Document	MDR / RoHS: 064080D-22103 RED: N/A
Basic UDI-DI	4538612010019G

Reusable Accessories for FX-8300 intended to be used in combination with CardiMax FX-8300.

No.	Device Name	Model	Type
1	Power Cable	CS-18-ST	-
2	Power Cable	CS-55-ST	-
3	Power Cable	CS-55-RA	-
4	Power Cable	CS-56-ST	-
5	Power Cable	CS-57-ST	-
6	Power Cable	CS-57-RA	-
7	Power Cable	CS-58-ST	-
8	Power Cable	CS-59-ST	-
9	Potential equalization cord	CE-11	-
10	Li-ion Battery Pack	BTE-001	-
11	Recording Paper	OP-358TE 145/30	-
12	Recording Paper	OP-382TE	-
13	SD Card	SD-2G	-
14	Serial 8P Cross Cable	CJS-03DA5-C	-
15	Chart Box	OAE-53A	-
16	PATIENT CABLE HANGER	OAE-47A	-
17	Trolley	OTE-05	-
18	Trolley	OTE-10	-
19	Card Reader Mounting Bracket	OAE-50A	-
20	Basket	OAE-52A	-
21	Storage Drawer	OAE-61A	-
22	Height Adjustment Spacer	OAO-1007A	-
23	Barcode Reader Holder	OAO-1008A	-