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 1	Fukuda Denshi Co., Ltd. 2-35-8 Hongo, Bunkyo-ku, Tokyo 113-8420 Japan
Location of Design 2	Fukuda Denshi Co., Ltd. 2-35-27 Hongo, Bunkyo-ku, Tokyo 113-8420 Japan
Location of Production	Fukuda Denshi Co., Ltd. Shiroi Factory 305-1 Naka, Shiroi-shi, Chiba 270-1495 Japan

Medical Device		
Product Category (Device Family)	Electrocardiograph	
Device Name	CardiMax FX-9800 *Refer to the Appendix 1 for details.	☒ MDR ((EU)2017/745) ☒ RoHS Directive (2011/65/EU) ☒ RE Directive (2014/53/EU)
	Reusable Accessories for FX-9800 *Refer to the Appendix 2 for details.	☒ MDR ((EU)2017/745) ☒ RoHS Directive (2011/65/EU) ☐ 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 B.V.
Address	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
SRN	NL-AR-000000116

Date of issue : 8 November 2024
Place of issue : Tokyo, Japan
Edition : 2nd
Date of 1st issue : 4 September 2024

Chie Kobayashi

Chie KOBAYASHI, PRRC
Manager
Quality Assurance Head Office

Appendix 1

Medical Device description	
Device Name	CardiMax FX-9800
Device Class	Class IIa
Device Classification Rule	Rule 10 (FX-9800, EE-50, EE-51, CIE-01B) / Rule 11 (FP-908A, FP-908LP) 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-23510 RED: 064080H-24803

Details of the system components:

1. Main unit

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
1.	CardiMax FX-9800	FX-9800	-	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.	Z12050 301	16231	4538612010009E	X	X

2. List of Class IIa Accessories:

Intended Purpose: These are the accessories to support FX-9800 or use to operate FX-9800.

*Refer to the following list for further details.

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
1.	ECG AMP Module	EE-50	-	EE-50 is a module to be installed in the main unit and to enable the additional ECG channel while switching the ECG of the patients or examinees.	Z12050 380	16231	4538612010009E	X	N/A
2.	ECG AMP Module for LP and 15-lead	EE-51	-	EE-51 is a module to be installed in the main unit, and to enable the additional ECG channel to be used for 15-lead ECG and Signal-Averaged ECG to detect Late Potential signal.	Z12050 380	16231	4538612010009E	X	N/A

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
3.	Wireless Patient Module	CIE-01B	-	CIE-01B is to transmit the ECG signal input from cables/leads connected to the patient to the electrocardiograph via wireless.	Z12050380	16231	4538612010009E	X	X
4.	ECG Interpretation Software	FP-908A	-	FP-908A includes the activation procedure to activate the optional software function. The optional software is the interpretation function to classify the measurement data in accordance with Minnesota Code classification and the grades.	Z12050382	58474	4538612010009E	N/A	N/A
5.	LP Testing Software	FP-908LP	-	FP-908LP includes 2 documents, the activation procedure to activate the optional software and the operation manual. The optional software function is Signal-Averaged ECG function to detect late potential (low amplitude) ECG signal.	Z12050382	58474	4538612010009E	N/A	N/A

Appendix 2

Medical Device description	
Device Name	Reusable Accessories for FX-9800
Device Class	Class I-sc (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-23510 RED: N/A

List of Class I-sc Reusable Accessories for FX-9800.

Intended Purpose: These are the accessories to support FX-9800 or use to operate FX-9800.

*Refer to the following list for further details.

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
1.	Patient Cable Hanger	OAE-47A	-	OAE-47A is a cable stand attached to the trolley and to secure 12-lead cable.	V9099	61434	4538612010019G	N/A	N/A
2.	Card Reader Mounting Bracket	OAE-50A	-	OAE-50A is a mounting bracket for fixing the ID card reader to the trolley.	V9099	61434	4538612010019G	N/A	N/A
3.	15-lead Patient Cable Hanger Attachment	OAE-51A	-	OAE-51A is an assembly kit to secure the 15-lead cable to the patient cable hanger.	Z12050380	61434	4538612010019G	N/A	N/A
4.	Basket	OAE-52A	-	OAE-52A is a storage basket being attached to the trolley.	V9099	61434	4538612010019G	N/A	N/A
5.	Chart Box	OAE-53A	-	OAE-53A is a wire basket attached to the trolley for storing documents or operating instructions.	V9099	61434	4538612010019G	N/A	N/A
6.	Back Side Cable Cover	OAE-57A	-	OAE-57A is a rear side cover to protect the cables conneted to the rear of main unit.	Z12050380	61434	4538612010019G	N/A	N/A
7.	Printing Paper Wire Bracket	OAE-58A	-	OAE-58A is a wire bracket to hold a folded recording paper for the trolley.	Z12050380	61434	4538612010019G	N/A	N/A
8.	Storage Drawer	OAE-61A	-	OAE-61A is a drawer-type storage attached to the trolley.	V9099	61434	4538612010019G	N/A	N/A
9.	Barcode Reader Holder	OAO-1008A	-	OAO-1008A is a holder to store a barcode reader.	V9099	61434	4538612010019G	N/A	N/A
10.	Keyboard Holder	OAE-65A	-	OAE-65A is a bracket to place a keyboard for the trolley.	Z12050380	61434	4538612010019G	N/A	N/A

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
11.	Height Adjustment Spacer	OAO-1007A	-	OAO-1007A is a bracket to be assembled to the pole of the trolley to adjust the height of the trolley.	V9099	61434	4538612010019G	N/A	N/A
12.	WPM dock	OAE-63A	-	OAE-63A is a holder attached to the trolley and to store the wireless patient module. OAE-63A can be used in conjunction with an AC adapter to charge the battery while storing the wireless patient module.	Z12050380	61434	4538612010019G	N/A	N/A
13.	Trolley	OTE-10	-	OTE-10 is a wheeled cart used for transporting the electrocardiograph and accessories.	Z12050380	40596	4538612010019G	N/A	N/A
14.	Li-ion Battery Pack	BTE-002	BTE-002	BTE-002 is a rechargeable batteries for the main unit.	Z12050380	36534	4538612010019G	X	N/A
15.	Li-ion Battery Pack	BTE-004	BTE-004	BTE-004 is a rechargeable batteries for wireless patient module.	Z12050380	36534	4538612010019G	X	N/A
16.	Potential Equalization Cord	CE-11	-	CE-11 is a cable connected to devices' potential equalization and used to avoid electric shock to the patient due to electrical potential difference between the devices when connecting multiple devices.	V9099	47487	4538612010019G	X	N/A
17.	Recording Paper	OP-69TE 210/30M	-	OP-69TE 210/30M is a roll-type thermal paper used for printing and recording ECG waveforms and measurement values.	Z12050380	16754	4538612010019G	N/A	N/A
18.	Recording paper	OP-621TE(EXP)	-	OP-621TE(EXP) is a fold-type thermal paper used for printing and recording ECG waveforms and measurement values.	Z12050380	16754	4538612010019G	N/A	N/A
19.	SD Card	SD-2G	-	SD-2G is an SD type memory card with 2GB to be used for the storage of patient information, examination data and measurement data.	V9099	62804	4538612010019G	X	N/A
20.	Power Cable	CS-18-ST	-	CS-18-ST is AC power cable for main unit.	V9099	45804	4538612010019G	X	N/A
21.	Power Cable	CS-55-ST	-	CS-55-ST is AC power cable for main unit.	V9099	45804	4538612010019G	X	N/A
22.	Power Cable	CS-57-ST	-	CS-57-ST is AC power cable for main unit.	V9099	45804	4538612010019G	X	N/A
23.	Patient Cable CME-03	CME-03FTAU	-	The patient cable, a component of this SYSTEM, is a noninvasive devices intended to be used to conduct electrical signals from a patient's heart, via an electrode attached to the surface of the chest to an electrocardiograph(ECG) machine. This is a reusable device, and a cable with connector. This device cannot be used in MR environment.	Z12050380	35562	4538612010019G	X	N/A

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
24.	Patient Cable CME-77	CME-77FJKU	-	The patient cable, a component of this SYSTEM, is a noninvasive devices intended to be used to conduct electrical signals from a patient's heart, via an electrode attached to the surface of the chest to an electrocardiograph(ECG) machine. This is a reusable device, and a cable with connector. This device cannot be used in MR environment.	Z12050380	35562	4538612010019G	X	N/A
25.	Patient Cable CME-77	CME-77FJKU-W	-	The patient cable, a component of this SYSTEM, is a noninvasive devices intended to be used to conduct electrical signals from a patient's heart, via an electrode attached to the surface of the chest to an electrocardiograph(ECG) machine. This is a reusable device, and a cable with connector. This device cannot be used in MR environment.	Z12050380	35562	4538612010019G	X	N/A
26.	Patient Cable CPE-01 Series	CPE-01BKPE	-	The patient cable, a component of this SYSTEM, is a noninvasive devices intended to be used to conduct electrical signals from a patient's heart, via an electrode attached to the surface of the chest to an electrocardiograph(ECG) machine. This is a reusable device, and a cable with connector. This device cannot be used in MR environment.	Z12050380	35562	4538612010019G	X	N/A