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. Shiroi Factory 305-1 Naka, Shiroi-shi, Chiba 270-1495 Japan

Medical Device		
Product Category	Measuring and Monitoring Device for Vital Signs	
Device Name	ECG, Respiration and SpO2 Transmitter model LX-8300M type LX-8300M *Refer to the Appendix 1 for details.	☒ MDR ((EU)2017/745) ☒ RoHS Directive (2011/65/EU) ☒ RE Directive (2014/53/EU)
	Reusable Accessories for LX-8300M *Refer to the Appendix 2 for details.	☒ MDR ((EU)2017/745) ☒ RoHS Directive (2011/65/EU) ☐ RE Directive (2014/53/EU)
	Disposable Accessories for LX-8300M *Refer to the Appendix 3 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
Address	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
SRN	NL-AR-000000116

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First issued : 2 September 2022

M. Onda

Makoto ONDA
PRRC, Senior Manager
Quality Assurance Headquarters

Appendix 1

Medical Device description	
Device Name	ECG, Respiration and SpO2 Transmitter model LX-8300M type LX-8300M
GMDN / EMDN Code	GMDN 33586 (General-purpose multi-parameter bedside monitor) EMDN Z12050803 (ELECTROCARDIOGRAPH TELEMETRY SYSTEM TRANSMITTERS)
Intended Purpose	This device intends to continuously transmit the vital signs to a specified monitor by wireless network. The measurable vital signs are electrocardiogram, respiration waveform, arterial oxygen saturation (SpO2) and pulse waveform.
Device Class	Class IIb
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: 063020H-21801 RED: 063020D-19C10
Basic UDI-DI	4538612022009X

Details of the system components:

No.	Device Name	Model	Type
1.	ECG, Respiration and SpO2 Transmitter model LX-8300M type LX-8300M	LX-8300M	LX-8300M

Appendix 2

Medical Device description	
Device Name	Reusable Accessories for LX-8300M
Intended Purpose	These are accessories to support LX-8300M or use to operate LX-8300M. LX-8300M intends to continuously transmit the vital signs to a specified monitor by wireless network. The measurable vital signs are electrocardiogram, respiration waveform, arterial oxygen saturation (SpO2) and pulse waveform.
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: 063020H-21801 RED: N/A
Basic UDI-DI	4538612022019Z

Reusable Accessories for LX-8300M intended to be used in combination with ECG, Respiration and SpO2 Transmitter model LX-8300M type LX-8300M.

No.	Device Name	Model	Type
1.	Neck Strap	OAT-03A	-
2.	SpO2 Cap	OAT-05A	-
3.	ECG Cap	OAT-06A	-

Appendix 3

Medical Device description	
Device Name	Disposable Accessories for LX-8300M
Intended Purpose	These are accessories to support LX-8300M or use to operate LX-8300M. LX-8300M intends to continuously transmit the vital signs to a specified monitor by wireless network. The measurable vital signs are electrocardiogram, respiration waveform, arterial oxygen saturation (SpO2) and pulse waveform.
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: 063020H-21801 RED: N/A
Basic UDI-DI	4538612022019Z

Disposable Accessories for LX-8300M intended to be used in combination with ECG, Respiration and SpO2 Transmitter model LX-8300M type LX-8300M.

No.	Device Name	Model	Type
1.	Disposable Portable Case	ABT-720D	-