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)	Measuring and Monitoring Device for Vital Signs	
Device Name	LX-1000 Series ECG, Respiration and SpO_2 Transmitter LX-1300 *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-1000 Series ECG, Respiration and SpO_2 Transmitter LX-1300 *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-1000 Series ECG, Respiration and SpO_2 Transmitter LX-1300 *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 B.V.
Address	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
SRN	NL-AR-000000116

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Yuki MITOBE, PRRC
Senior Manager
Quality Assurance Head Office

Appendix 1

Medical Device description	
Device Name	LX-1000 Series ECG, Respiration and SpO_2 Transmitter LX-1300
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-24702 RED : 063020D-25C03

Details of the system components:

1. Main unit

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 (SpO_2) and pulse waveform.

No.	Device Name	Model	Type	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
1.	LX-1000 Series ECG, Respiration and SpO_2 Transmitter LX-1300	LX-1300	LX-1300N	Z12050803	33586	4538612022009X	X	X
2.	LX-1000 Series ECG, Respiration and SpO_2 Transmitter LX-1300	LX-1300	LX-1300M	Z12050803	33586	4538612022009X	X	X
3.	LX-1000 Series ECG, Respiration and SpO_2 Transmitter LX-1300	LX-1300	LX-1300E	Z12050803	33586	4538612022009X	X	X

Appendix 2

Medical Device description	
Device Name	Reusable Accessories for LX-1000 Series ECG, Respiration and SpO_2 Transmitter LX-1300
Device Class	Class I-sc (self-certified)
Device Classification Rule	Rule 1 Annex VIII of Medical Devices Regulation (EU) 2017/745
EEE Categories	N/A
RE Directive	N/A
Technical Document	MDR : 063020H-24702 RoHS : N/A RED : N/A

List of Class I-sc Reusable Accessories for LX-1000 Series ECG, Respiration and SpO_2 Transmitter LX-1300.

Intended Purpose:

These are the accessories to be used together with LX-1000 Series ECG, Respiration and SpO_2 Transmitter LX-1300 to enable it to be used in accordance with its intended purpose.

*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.	Neck Strap	OAT-03A	-	OAT-03A is a strap for carrying a telemetry transmitter around the patient's neck.	Z1203020280	37685	4538612022019Z	-	-
2.	Silicone Cover for LX-1300	ABT-1300C	-	ABT-1300C is a portable case for carrying a telemetry transmitter.	Z12030680	33586	4538612022019Z	-	-

Appendix 3

Medical Device description	
Device Name	Disposable Accessories for LX-1000 Series ECG, Respiration and SpO_2 Transmitter LX-1300
Device Class	Class I-sc (self-certified)
Device Classification Rule	Rule 1 Annex VIII of Medical Devices Regulation (EU) 2017/745
EEE Categories	N/A
RE Directive	N/A
Technical Document	MDR : 063020H-24702 RoHS : N/A RED : N/A

List of Class I-sc Disposable Accessories for LX-1000 Series ECG, Respiration and SpO_2 Transmitter LX-1300.

Intended Purpose:

These are the accessories to be used together with LX-1000 Series ECG, Respiration and SpO_2 Transmitter LX-1300 to enable it to be used in accordance with its intended purpose.

*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.	Disposable Portable Case	ABT-720D	-	ABT-720D is a disposable portable case for carrying a telemetry transmitter.	Z1203020280	31072	4538612022019Z	-	-