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	Central Telemetry Receiver LW-1000 *Refer to the Appendix 1 for details.	☒ MDR ((EU)2017/745) ☒ RoHS Directive (2011/65/EU) ☒ RE Directive (2014/53/EU)
	Reusable Accessories for LW-1000 (Vital Signs Telemetry Receiver) *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
Address	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
SRN	NL-AR-000000116

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Takashi Nomura
General Manager
Quality Assurance Department

Appendix 1

Medical Device description	
Device Name	Central Telemetry Receiver LW-1000
GMDN / EMDN Code	GMDN 36365 (Electrocardiography monitoring system receiver) EMDN Z12030602 (VITAL SIGNS TELEMETRY RECEIVERS)
Intended Purpose	This device is a telemetry receiver to monitor the conditions of the patients. It deals with the following vital sign parameters, which are measured and transmitted by the specified bedside monitors and /or the telemeters for use in combination. The vital signs are electrocardiogram, heart rate, respiration rate, body temperature, arterial oxygen saturation (SpO2), pulse rate, invasive blood pressure, non-invasive blood pressure and CO2 concentration.
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-22C33 RED: 063020D-23210
Basic UDI-DI	453861202300A4

Details of the system components:

No.	Device Name	Model	Type
1	Central Telemetry Receiver LW-1000	LW-1000	LW-1080

Appendix 2

Medical Device description	
Device Name	Reusable Accessories for LW-1000
EMDN Code	Z12030602 (VITAL SIGNS TELEMETRY RECEIVERS)
Intended Purpose	These are accessories to support LW-1000 or use to operate LW-1000. LW-1000 is a telemetry receiver to monitor the conditions of the patients. It deals with the following vital sign parameters, which are measured and transmitted by the specified bedside monitors and /or the telemeters for use in combination. The vital signs are electrocardiogram, heart rate, respiration rate, body temperature, arterial oxygen saturation (SpO2), pulse rate, invasive blood pressure, non-invasive blood pressure and CO2 concentration.
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)
Technical Document	MDR / RoHS: 063020H-22C33
Basic UDI-DI	453861202301A6

Reusable Accessories for LW-1000 intended to be used in combination with Central Telemetry Receiver LW-1000.

No.	Device Name	Model	Type
1	Power Cable	CS-18	-
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	Ethernet Branch Cable	CJ-522A	-
10	Ethernet Branch Cable	CJ-522B	-
11	Ethernet Branch Cable	CJ-522C	-
12	Ethernet Branch Cable	CJ-522D	-
13	Ethernet Branch Cable	CJ-522E	-
14	Ethernet Branch Cable STP	CJ-523A	-
15	Ethernet Branch Cable STP	CJ-523B	-
16	Ethernet Branch Cable STP	CJ-523C	-
17	Ethernet Branch Cable STP	CJ-523D	-
18	Ethernet Branch Cable STP	CJ-523E	-
19	Unit Connection Cable	CJO-09SS1.5	-
20	Unit Connection Cable	CJO-09SS5	-
21	SD Card	FSD-2G	-
22	RS-232C Cross Cable	CJ-725	-
23	Trolley(L)	OTO-16L	-
24	Mounting Bracket for LW-1000	OAO-1012A	-