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	DYNASCOPE 1000 Series DS-1700 System *Refer to the Appendix 1 for details.	☒ MDR ((EU)2017/745) ☒ RoHS Directive (2011/65/EU) ☒ RE Directive (2014/53/EU)
	Reusable Accessories for DS-1700 (Central Information Computing Systems) *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

Date of issue : 28 July 2023
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Takashi Nomura
General Manager
Quality Assurance Department

Appendix 1

Medical Device description	
Device Name	DYNASCOPE 1000 Series DS-1700 System
GMDN / EMDN Code	GMDN 38470 (Patient monitoring system central station monitor) EMDN Z12030201 (CENTRAL INFORMATION COMPUTING SYSTEMS) Z12030602 (VITAL SIGNS TELEMETRY RECEIVERS)
Intended Purpose	This device is a central monitor 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, CO2 concentration, O2 concentration and anesthetic gas concentration (including N2O, halothane, isoflurane, enflurane, sevoflurane and desflurane).
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-20728 RED: 063020D-21503
Basic UDI-DI	4538612021009S

Details of the system components:

No.	Device Name	Model	Type
1	DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1708RE
2	DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1708R
3	DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1708E
4	DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1708
5	DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1700LRE
6	DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1700LR
7	DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1700LE
8	DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1700L

List of Accessories for Class IIb medical device:

No.	Device Name	Model	Type
1	Recorder Unit	HR-800	HR-800

Appendix 2

Medical Device description	
Device Name	Reusable Accessories for DS-1700
EMDN Code	Z12030201 (CENTRAL INFORMATION COMPUTING SYSTEMS) Z12030602 (VITAL SIGNS TELEMETRY RECEIVERS)
Intended Purpose	These are accessories to support DS-1700 or use to operate DS-1700. DS-1700 is a central monitor 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, CO2 concentration, O2 concentration and anesthetic gas concentration (including N2O, halothane, isoflurane, enflurane, sevoflurane and desflurane).
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-20728
Basic UDI-DI	4538612021019U

Reusable Accessories for DS-1700 intended to be used in combination with DYNASCOPE 1000 Series DS-1700 System.

No.	Device Name	Model	Type
1	Recording Paper	OP050-02TDR	-
2	Unit Connection Cable	CJO-09SS0.3	-
3	Unit Connection Cable	CJO-09SS1.5	-
4	Power Cable	CS-33	-
5	Power Cable	CS-55-ST	-
6	Power Cable	CS-55-RA	-
7	Power Cable	CS-56-ST	-
8	Power Cable	CS-57-ST	-
9	Power Cable	CS-57-RA	-
10	Power Cable	CS-58-ST	-
11	Power Cable	CS-59-ST	-
12	SD Card	FSD-64G	-
13	Lithium-Ion Battery Pack	BTO-005	-
14	Ethernet Branch Cable	CJ-522A	-
15	Ethernet Branch Cable	CJ-522B	-
16	Ethernet Branch Cable	CJ-522C	-
17	Ethernet Branch Cable	CJ-522D	-
18	Ethernet Branch Cable	CJ-522E	-
19	Ethernet Branch Cable STP	CJ-523A	-
20	Ethernet Branch Cable STP	CJ-523B	-
21	Ethernet Branch Cable STP	CJ-523C	-
22	Ethernet Branch Cable STP	CJ-523D	-
23	Ethernet Branch Cable STP	CJ-523E	-

Appendix 2 (continued)

No.	Device Name	Model	Type
24	Connection Cable	CJ-530A	-
25	Connection Cable	CJ-530B	-
26	Connection Cable	CJ-530C	-
27	LAN Interface Cable STP	CJ-533A	-
28	LAN Interface Cable STP	CJ-533B	-
29	LAN Interface Cable STP	CJ-533C	-
30	IR Remote Control Unit	CF-800	CF-820
31	RS-232C Cross Cable	CJ-725	-
32	Relay Cable (Straight)	CJ-726	-
33	Serial Converter Cable	CJ-756	-
34	Relay Cable	CJ-502	-
35	GCX attachment for Monitor	OAO-70A	-
36	Trolley(L)	OTO-16L	-
37	Card Reader Mounting Bracket	OAE-50A	-
38	Basket	OAE-52A	-
39	Chart Box	OAE-53A	-
40	Storage Drawer	OAE-61A	-
41	Height Adjustment Spacer	OAO-1007A	-
42	Barcode Reader Holder	OAO-1008A	-
43	Mounting Bracket for LW-1000	OAO-1012A	-
44	Lower Trolley Unit for Monitor	OTO-13	-
45	Upper Trolley Unit for Monitor	OAO-8400	-
46	Storage Box for Trolley	OAO-91A	-