

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

Medical Device		
Product Category	Measuring and Monitoring Device for Vital Signs	
Device Name	DYNASCOPE 8000 Series DS-8007 System *Refer to the Appendix 1 for details.	<input checked="" type="checkbox"/> MDR ((EU)2017/745) <input checked="" type="checkbox"/> RoHS Directive (2011/65/EU) <input type="checkbox"/> RE Directive (2014/53/EU)
	Reusable Accessories for DS-8007 *Refer to the Appendix 2 for details.	<input checked="" type="checkbox"/> MDR ((EU)2017/745) <input checked="" type="checkbox"/> RoHS Directive (2011/65/EU) <input checked="" type="checkbox"/> 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
 Place of issue : Tokyo, Japan
 Edition : 2nd
 First issued : 30 November 2022



 Takashi Nomura
 General Manager
 Quality Assurance Department

Appendix 1

Medical Device description	
Device Name	DYNASCOPE 8000 Series DS-8007 System
GMDN / EMDN Code	GMDN 33586 (General-purpose multi-parameter bedside monitor) EMDN Z1203020201 (MULTI-PARAMETER PATIENT BEDSIDE MONITORS)
Intended Purpose	This device intends to measure the vital signs to monitor patient condition by displaying and printing the measurement data on this device or central monitor and to generate alarm when necessary. 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, cardiac output (CO) and blood temperature.
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	N/A
Technical Document	MDR / RoHS: 063150H-22704 RED: N/A
Basic UDI-DI	4538612020009M

Details of the system components:

No.	Device Name	Model	Type
1	DYNASCOPE 8000 Series DS-8007 System	DS-8007	DS-8007N
2	DYNASCOPE 8000 Series DS-8007 System	DS-8007	DS-8007M

List of Accessories for Class IIb medical device:

No.	Device Name	Model	Type
1	AC Unit	DSA-81	DSA-81
2	DS-8007 Adapter	DSA-82	DSA-82
3	CO2 Gas Unit	HCP-820	HCP-820
4	CO2 Gas Unit	HCP-810	HCP-810
5	GAS Unit I/F	HPD-820	HPD-820
6	GAS Unit I/F	HPD-810	HPD-810
7	BISx I/F Unit	HBX-800	HBX-800
8	Recorder Unit	HR-800	HR-800

Appendix 2

Medical Device description	
Device Name	Reusable Accessories for DS-8007
EMDN Code	Z1203020201 (MULTI-PARAMETER PATIENT BEDSIDE MONITORS)
Intended Purpose	<p>These are accessories to support DS-8007 or use to operate DS-8007. DS-8007 intends to measure the vital signs to monitor patient condition by displaying and printing the measurement data on this device or central monitor and to generate alarm when necessary.</p> <p>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, cardiac output (CO) and blood temperature.</p>
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	Annex II of Directive 2014/53/EU
Technical Document	MDR / RoHS: 063150H-22704 RED: 063020D-17614
Basic UDI-DI	4538612020019P

Reusable Accessories for DS-8007 intended to be used in combination with DYNASCOPE 8000 Series DS-8007 System.

No.	Device Name	Model	Type
1	Bed Mount for Patient Monitor	OAO-102A	-
2	AUX Unit Mounting Bracket	OAO-103A	-
3	Countertop for Patient Monitor	OAO-104A	-
4	Mounting Bracket for Pole Clamp	OAO-105A	-
5	GCX Attachment for Monitor	OAO-70A	-
6	HLX Holder for DSA-81	OAO-111A	-
7	Recording Paper	OP050-02TDR	-
8	TM XMTR Module HLX-801	HLX-801	-
9	Lithium-ion Battery Pack	BTO-008	BTO-008
10	Unit Connection Cable	CJO-09SS0.3	-
11	Unit Connection Cable	CJO-09SS1.5	-
12	Unit Connection Cable	CJO-09SS5	-
13	3ch Analog Output Cable	CJO-26JJ0.5	-
14	3ch Analog Output Cable	CJO-26JJ2.7	-
15	AUX Connection Cable LEM	CJO-25TR0.65	-
16	AUX Connection Cable LEM	CJO-25TR1.5	-
17	AUX Connection Cable LEM	CJO-25TR2.7	-
18	SD Card	FSD-8GA	-
19	SD Card	SD-16G	-
20	12-Lead Analysis Optional Software	DS-8007-12LA	-
21	Module Connection Cable	CJO-08SS0.3	-
22	Module Connection Cable	CJO-08SS1.5	-
23	Module Connection Cable	CJO-08SS3.5	-
24	Module Connection Cable	CJO-08SS5	-
25	Module Connection Cable	CJO-08SS10	-

Appendix 2 (continued)

No.	Device Name	Model	Type
26	Earth wire	CE-01A	-
27	Ethernet Branch Cable	CJ-522A	-
28	Ethernet Branch Cable	CJ-522B	-
29	Ethernet Branch Cable	CJ-522C	-
30	Ethernet Branch Cable	CJ-522D	-
31	Ethernet Branch Cable	CJ-522E	-
32	BIS Monitor interface cable	CJO-03RS4	-
33	RS-232C Cross Cable	CJ-725	-
34	SV-300 interface cable	CJ-401RI-70SV3	-
35	Relay Cable	CJ-402RI-70SVi	-
36	PB700/800 serial interface cable	CJ-403RI-70PB	-
37	BIS Monitor interface cable	CJ-407RI-70BIS	-
38	Serial Converter Cable	CJ-756	-
39	Power Cable	CS-18	-
40	Power Cable	CS-55-ST	-
41	Power Cable	CS-55-RA	-
42	Power Cable	CS-56-ST	-
43	Power Cable	CS-57-ST	-
44	Power Cable	CS-57-RA	-
45	Power Cable	CS-58-ST	-
46	Power Cable	CS-59-ST	-

ECG Accessory

No.	Device Name	Model	Type
47	ECG Relay Cable	CIO-05CTP-3NU	-
48	ECG Relay Cable	CIO-05CTP-4NU	-
49	ECG Relay Cable	CIO-05CTP-5NU	-
50	ECG Relay Cable	CIO-05CTP-10NU	-
51	ECG Relay Cable	CIO-08CTP-3EU	-
52	ECG Relay Cable	CIO-08CTP-5EU	-
53	Patient Cable Adapter	CIZ-173DIN-3-U	-
54	Patient Cable Adapter	CIZ-173DIN-5-U	-
55	Patient Cable Adapter	CIZ-173DIN-C-U	-

Blood Pressure Accessory

No.	Device Name	Model	Type
56	BP Relay Cable	CJO-P01B-SB3.6	-
57	2ch BP Relay Cable	CJO-P01B-DB0.8	-
58	2ch BP Relay Cable	CJO-P01B-DB4.3	-
59	2ch BP Conversion Cable	CJO-P01B-DJ0.5	-

Temperature Accessory

No.	Device Name	Model	Type
60	2ch Temperature Relay Cable	CJO-P01T-DA0.5	-
61	2ch Temperature Relay Cable	CJO-P01T-DA4.0	-

Appendix 2 (continued)

CO Accessory

No.	Device Name	Model	Type
62	Catheter Relay Cable	CJO-P01C-C2.4	-
63	Flow-Through Sensor Relay Cable	CJO-P01C-F2.4	-
64	In-line Sensor Relay Cable	CJO-P01C-L2.4	-
65	Injectate Probe Relay Cable	CJO-P01C-T2.4	-

NIBP Accessory

No.	Device Name	Model	Type
66	Air Hose	OA-80APS1.5-S	-
67	Air Hose	OA-80APS3.5-S	-
68	Air Hose	OA-80NE1.5-S	-
69	Air Hose	OA-80NE3.5-S	-