

## 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-8200 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-8200 *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

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 Takashi Nomura  
 General Manager  
 Quality Assurance Department

**Appendix 1**

<b>Medical Device description</b>	
Device Name	DYNASCOPE 8000 Series DS-8200 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-24204 RED: N/A
Basic UDI-DI	4538612020009M

Details of the system components:

No.	Device Name	Model	Type
1	Display Unit	LC-8200	LC-8210
2	HS Adapter	HSB-80	HSB-80
3	Base Unit	BS-8210	BS-8210
4	Super Unit	HS-8000	HS-8312M
5	Super Unit	HS-8000	HS-8312N

List of Accessories for Class IIb medical device:

No.	Device Name	Model	Type
1	CO2 Gas Unit	HCP-810	HCP-810
2	GAS Unit I/F	HPD-810	HPD-810
3	Recorder Unit	HR-800	HR-800

**Appendix 2**

<b>Medical Device description</b>	
Device Name	Reusable Accessories for DS-8200
EMDN Code	Z1203020201 (MULTI-PARAMETER PATIENT BEDSIDE MONITORS)
Intended Purpose	<p>These are accessories to support DS-8200 or use to operate DS-8200. DS-8200 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-24204 RED: 063020D-17614
Basic UDI-DI	4538612020019P

Reusable Accessories for DS-8200 intended to be used in combination with DYNASCOPE 8000 Series DS-8200 System.

No.	Device Name	Model	Type
1	Countertop for DS-8200	OAO-68A	-
2	Bed Mount for DS-8200	OAO-69A	-
3	GCX Attachment for Monitor	OAO-70A	-
4	VESA Attachment for LC-8210	OAO-71A	-
5	Gas Unit / External Output Box Mounting Bracket	OAO-72A	-
6	Recorder Mounting Bracket for Countertop	OAO-74A	-
7	Recording Paper	OP050-02TDR	-
8	TM XMTR Module HLX-801	HLX-801	-
9	HLX-801 Installation Cover	OAT-02A	-
10	Lithium-Ion Battery Pack	BTO-008	BTO-008
11	IR Remote Control Unit	CF-800	CF-820
12	CF Card	FCF-128	-
13	CF Card	FCF-1000	-
14	CF Card	FCF-16GA	-
15	SD Card	SD-1G	-
16	SD Card	SD-8G	-
17	External Output Box	CJO-C01Q-SJ0.3	-
18	Unit Connection Cable	CJO-09SS0.3	-
19	Unit Connection Cable	CJO-09SS1.5	-
20	Unit Connection Cable	CJO-09SS5	-
21	Network Cable	CJO-14SS1.5	-
22	Network Cable	CJO-14SS2.5	-
23	Network Cable	CJO-14SS5	-

**Appendix 2 (continued)**

No.	Device Name	Model	Type
24	Network Cable	CJO-14SS10	-
25	Network Cable	CJO-14SS20	-
26	AUX Connection Cable	CJO-15RR0.17	-
27	AUX Connection Cable	CJO-15RR0.65	-
28	AUX Connection Cable	CJO-15RR1.5	-
29	AUX Connection Cable	CJO-15RR3	-
30	Display Unit Extension Cable	CJO-16SS1.5	-
31	Display Unit Extension Cable	CJO-16SS3	-
32	Display Unit Extension Cable	CJO-16SS5	-
33	Earth wire	CE-01A	-
34	12-Lead Analysis Optional Software	DS-8200-12LA	-
35	Ethernet Branch Cable	CJ-522A	-
36	Ethernet Branch Cable	CJ-522B	-
37	Ethernet Branch Cable	CJ-522C	-
38	Ethernet Branch Cable	CJ-522D	-
39	Ethernet Branch Cable	CJ-522E	-
40	BIS Monitor interface cable	CJO-03RS4	-
41	RS-232C Cross cable	CJ-725	-
42	SV-300 interface cable	CJ-401RI-70SV3	-
43	Relay Cable	CJ-402RI-70SVi	-
44	PB700/800 serial interface cable	CJ-403RI-70PB	-
45	BIS Monitor interface cable	CJ-407RI-70BIS	-
46	Serial Converter Cable	CJ-756	-
47	Power Cable	CS-18	-
48	Power Cable	CS-55-ST	-
49	Power Cable	CS-55-RA	-
50	Power Cable	CS-56-ST	-
51	Power Cable	CS-57-ST	-
52	Power Cable	CS-57-RA	-
53	Power Cable	CS-58-ST	-
54	Power Cable	CS-59-ST	-
55	Trolley (S)	OTO-16S	-
56	Mounting Bracket for HR-800	OAO-1003A	-
57	Balancer for Trolley	OAO-1011A	-

**ECG Accessory**

No.	Device Name	Model	Type
58	ECG Relay Cable	CIO-05CTP-3NU	-
59	ECG Relay Cable	CIO-05CTP-4NU	-
60	ECG Relay Cable	CIO-05CTP-5NU	-
61	ECG Relay Cable	CIO-05CTP-10NU	-
62	ECG Relay Cable	CIO-08CTP-3EU	-
63	ECG Relay Cable	CIO-08CTP-5EU	-
64	Patient Cable Adapter	CIZ-173DIN-3-U	-
65	Patient Cable Adapter	CIZ-173DIN-5-U	-
66	Patient Cable Adapter	CIZ-173DIN-C-U	-



**Appendix 2 (continued)**

**Blood Pressure Accessory**

No.	Device Name	Model	Type
67	BP Relay Cable	CJO-P01B-SB3.6	-
68	2ch BP Relay Cable	CJO-P01B-DB0.8	-
69	2ch BP Relay Cable	CJO-P01B-DB4.3	-
70	2ch BP Conversion Cable	CJO-P01B-DJ0.5	-

**Temperature Accessory**

No.	Device Name	Model	Type
71	2ch Temperature Relay Cable	CJO-P01T-DA0.5	-
72	2ch Temperature Relay Cable	CJO-P01T-DA4.0	-

**CO Accessory**

No.	Device Name	Model	Type
73	Catheter Relay Cable	CJO-P01C-C2.4	-
74	Flow-Through Sensor Relay Cable	CJO-P01C-F2.4	-
75	In-Line Sensor Relay Cable	CJO-P01C-L2.4	-
76	Injectate Probe Relay Cable	CJO-P01C-T2.4	-

**NIBP Accessory**

No.	Device Name	Model	Type
77	Air Hose	OA-80APS1.5-S	-
78	Air Hose	OA-80APS3.5-S	-
79	Air Hose	OA-80NE1.5-S	-
80	Air Hose	OA-80NE3.5-S	-