

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-8100 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-8100 *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-8100 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-24203 RED: N/A
Basic UDI-DI	4538612020009M

Details of the system components:

No.	Device Name	Model	Type
1	DYNASCOPE 8000 Series DS-8100 System	DS-8100	DS-8100N
2	DYNASCOPE 8000 Series DS-8100 System	DS-8100	DS-8100M

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/Expansion Port Unit	HR-811	HR-811
4	Recorder Unit	HR-810	HR-810
5	Expansion Port Unit	CU-810	CU-810

Appendix 2

Medical Device description	
Device Name	Reusable Accessories for DS-8100
EMDN Code	Z1203020201 (MULTI-PARAMETER PATIENT BEDSIDE MONITORS)
Intended Purpose	<p>These are accessories to support DS-8100 or use to operate DS-8100. DS-8100 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-24203 RED: 063020D-17614
Basic UDI-DI	4538612020019P

Reusable Accessories for DS-8100 intended to be used in combination with DYNASCOPE 8000 Series DS-8100 System.

No.	Device Name	Model	Type
1	HCP Attachment Case for DS-8100	OAO-65A	-
2	Stand for DS-8100	OAO-66A	-
3	Rail/Pole Clamp for DS-8100 (VESA75mm)	OAO-84A	-
4	Bed Mount for DS-8100 (VESA75mm)	OAO-85A	-
5	HCP Fixing Bracket for DS-8100	OAO-86A	-
6	Counter Bracket (for OAO-66A)	OAO-87A	-
7	Clip Bracket for DS-8100	OAO-90A	-
8	Recording Paper	OP050-02TDR	-
9	TM XMTR Module HLX-801	HLX-801	-
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	Network Cable	CJO-14SS1.5	-
18	Network Cable	CJO-14SS2.5	-
19	Network Cable	CJO-14SS5	-
20	Network Cable	CJO-14SS10	-
21	Network Cable	CJO-14SS20	-
22	AUX Connection Cable	CJO-15RR0.17	-
23	AUX Connection Cable	CJO-15RR0.65	-
24	AUX Connection Cable	CJO-15RR1.5	-

Appendix 2 (continued)

No.	Device Name	Model	Type
25	AUX Connection Cable	CJO-15RR3	-
26	Potential equalization cord	CE-11	-
27	Earth wire	CE-01A	-
28	Ethernet Branch Cable	CJ-522A	-
29	Ethernet Branch Cable	CJ-522B	-
30	Ethernet Branch Cable	CJ-522C	-
31	Ethernet Branch Cable	CJ-522D	-
32	Ethernet Branch Cable	CJ-522E	-
33	BIS Monitor interface cable	CJO-03RS4	-
34	RS-232C Cross cable	CJ-725	-
35	SV-300 interface cable	CJ-401RI-70SV3	-
36	Relay Cable	CJ-402RI-70SVi	-
37	PB700/800 serial interface cable	CJ-403RI-70PB	-
38	BIS Monitor interface cable	CJ-407RI-70BIS	-
39	Serial Converter Cable	CJ-756	-
40	Power Cable	CS-18	-
41	Power Cable	CS-55-ST	-
42	Power Cable	CS-55-RA	-
43	Power Cable	CS-56-ST	-
44	Power Cable	CS-57-ST	-
45	Power Cable	CS-57-RA	-
46	Power Cable	CS-58-ST	-
47	Power Cable	CS-59-ST	-
48	Trolley (S)	OTO-16S	-
49	Detachable Attachment for Patient Monitor	OAO-1000	-
50	Mounting Bracket for DS-8100	OAO-1001A	-

ECG Accessory

No.	Device Name	Model	Type
51	ECG Relay Cable	CIO-05CTP-3NU	-
52	ECG Relay Cable	CIO-05CTP-4NU	-
53	ECG Relay Cable	CIO-05CTP-5NU	-
54	ECG Relay Cable	CIO-08CTP-3EU	-
55	ECG Relay Cable	CIO-08CTP-5EU	-
56	Patient Cable Adapter	CIZ-173DIN-3-U	-
57	Patient Cable Adapter	CIZ-173DIN-5-U	-

Blood Pressure Accessory

No.	Device Name	Model	Type
58	BP Relay Cable	CJO-P01B-SB3.6	-
59	2ch BP Relay Cable	CJO-P01B-DB0.8	-
60	2ch BP Relay Cable	CJO-P01B-DB4.3	-
61	2ch BP Conversion Cable	CJO-P01B-DJ0.5	-

Temperature Accessory

No.	Device Name	Model	Type
62	2ch Temperature Relay Cable	CJO-P01T-DA0.5	-
63	2ch Temperature Relay Cable	CJO-P01T-DA4.0	-

Appendix 2 (continued)

CO Accessor

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

NIBP Accessory

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