

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-8500 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-8500 *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-8500 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, O2 concentration, cardiac output (CO), blood temperature 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	N/A
Technical Document	MDR / RoHS: 063150H-24205 RED: N/A
Basic UDI-DI	4538612020009M

Details of the system components:

No.	Device Name	Model	Type
1	DYNASCOPE 8000 Series DS-8500 System	DSC-8500	DSC-8510
2	DYNASCOPE 8000 Series DS-8500 System	DSC-8500	DSC-8530
3	Display Unit	LC-8000	LC-8015TC
4	Display Unit	LC-8000	LC-8019TC

List of Accessories for Class IIb medical device:

No.	Device Name	Model	Type
1	Super Unit	HS-8000	HS-8312M
2	Super Unit	HS-8000	HS-8312N
3	Multi Module	HM-800	HM-800
4	SpO ₂ Module	HG-800	HG-810
5	SpO ₂ Module	HG-800	HG-820
6	Multiport Module	HP-800	HP-800
7	HS Adapter	HSA-80	HSA-80
8	Input Box	IB-8000	IB-8004
9	CO ₂ Gas Unit	HCP-810	HCP-810
10	GAS Unit I/F	HPD-810	HPD-810
11	Recorder Unit	HR-800	HR-800
12	Multigas Unit I/F	MGU-800	MGU-801P
13	Multigas Unit I/F	MGU-800	MGU-802
14	Multigas Unit I/F	MGU-810	MGU-811P
15	Multigas Unit I/F	MGU-810	MGU-812
16	BISx I/F Unit	HBX-800	HBX-800

Appendix 2

Medical Device description	
Device Name	Reusable Accessories for DS-8500
EMDN Code	Z1203020201 (MULTI-PARAMETER PATIENT BEDSIDE MONITORS)
Intended Purpose	<p>These are accessories to support DS-8500 or use to operate DS-8500. DS-8500 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, O2 concentration, cardiac output (CO), blood temperature and anesthetic gas concentration (including N2O, halothane, isoflurane, enflurane, sevoflurane and desflurane).</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-24205 RED: 063020D-17614
Basic UDI-DI	4538612020019P

Reusable Accessories for DS-8500 intended to be used in combination with DYNASCOPE 8000 Series DS-8500 System.

No.	Device Name	Model	Type
1	TM XMTR Module HLX-801	HLX-801	-
2	Input Box Spacer	OAO-47A	-
3	IB Clamp Base	OAO-51A	-
4	HS Fixing Base	OAO-52A	-
5	HLX Holder for DS-8500	OAO-40A	-
6	HLX-801 Mounting Bracket	OAT-8185A	-
7	Main Stand for DS-8500	OAO-44A	-
8	HS Attachment Spacer	OAO-46A	-
9	HS Rail Clamp	OAO-48A	-
10	HS Suspended Base	OAO-49A	-
11	Cover Panel	OAO-45A	-
12	HS Pole Clamp	OAO-50A	-
13	Recording Paper	OP050-02TDR	-
14	IR Remote Control Unit	CF-800	CF-820
15	CF Card	FCF-128	-
16	CF Card	FCF-1000	-
17	CF Card	FCF-16GA	-
18	SD Card	SD-1G	-
19	SD Card	SD-8G	-
20	External Output Box	CJO-C01Q-SJ0.3	-
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	Unit Connection Cable	CJO-09SS0.3	-
27	Unit Connection Cable	CJO-09SS1.5	-
28	Unit Connection Cable	CJO-09SS5	-
29	AUX Connection Cable	CJO-15RR0.17	-
30	AUX Connection Cable	CJO-15RR0.65	-
31	AUX Connection Cable	CJO-15RR1.5	-
32	AUX Connection Cable	CJO-15RR3	-
33	Earth wire	CE-01A	-
34	12-Lead Analysis Optional Software	DS-8500-12LA	-
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	Display Unit Connection Cable	CJ-731B	-
41	Display Unit Connection Cable	CJ-731C	-
42	Display Unit Connection Cable	CJ-731D	-
43	BIS Monitor interface cable	CJO-03RS4	-
44	RS-232C Cross cable	CJ-725	-
45	SV-300 interface cable	CJ-401RI-70SV3	-
46	Relay Cable	CJ-402RI-70SVi	-
47	PB700/800 serial interface cable	CJ-403RI-70PB	-
48	Vigilance connection cable	CJ-406RI-70Vigi	-
49	BIS Monitor interface cable	CJ-407RI-70BIS	-
50	Serial Converter Cable	CJ-756	-
51	Power Cable	CS-33	-
52	Power Cable	CS-55-ST	-
53	Power Cable	CS-55-RA	-
54	Power Cable	CS-56-ST	-
55	Power Cable	CS-57-ST	-
56	Power Cable	CS-57-RA	-
57	Power Cable	CS-58-ST	-
58	Power Cable	CS-59-ST	-
59	ECG Relay Cable	CJO-05CTP-3NU	-
60	ECG Relay Cable	CJO-05CTP-4NU	-
61	ECG Relay Cable	CJO-05CTP-5NU	-
62	ECG Relay Cable	CJO-05CTP-10NU	-
63	ECG Relay Cable	CJO-08CTP-3EU	-
64	ECG Relay Cable	CJO-08CTP-5EU	-
65	Patient Cable Adapter	CIZ-173DIN-3-U	-
66	Patient Cable Adapter	CIZ-173DIN-5-U	-
67	Patient Cable Adapter	CIZ-173DIN-C-U	-
68	BP Relay Cable	CJO-P01B-SB3.6	-
69	2ch BP Relay Cable	CJO-P01B-DB0.8	-
70	2ch BP Relay Cable	CJO-P01B-DB4.3	-
71	2ch BP Conversion Cable	CJO-P01B-DJ0.5	-
72	2ch Temperature Relay Cable	CJO-P01T-DA0.5	-
73	2ch Temperature Relay Cable	CJO-P01T-DA4.0	-

Appendix 2 (continued)

No.	Device Name	Model	Type
74	Catheter Relay Cable	CJO-P01C-C2.4	-
75	Flow-Through Sensor Relay Cable	CJO-P01C-F2.4	-
76	In-Line Sensor Relay Cable	CJO-P01C-L2.4	-
77	Injectate Probe Relay Cable	CJO-P01C-T2.4	-
78	Air Hose	OA-80APS1.5-S	-
79	Air Hose	OA-80APS3.5-S	-
80	Air Hose	OA-80NE1.5-S	-
81	Air Hose	OA-80NE3.5-S	-