

## 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-8400 System *Refer to the Appendix 1 for details. <table border="0" style="float: right;"> <tr><td><input checked="" type="checkbox"/></td><td>MDR ((EU)2017/745)</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>RoHS Directive (2011/65/EU)</td></tr> <tr><td><input type="checkbox"/></td><td>RE Directive (2014/53/EU)</td></tr> </table>	<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)
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<input type="checkbox"/>	RE Directive (2014/53/EU)						
Reusable Accessories for DS-8400 *Refer to the Appendix 2 for details.	<table border="0" style="float: right;"> <tr><td><input checked="" type="checkbox"/></td><td>MDR ((EU)2017/745)</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>RoHS Directive (2011/65/EU)</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>RE Directive (2014/53/EU)</td></tr> </table>	<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)
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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-8400 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)
Technical Document	MDR / RoHS: 063150H-23A04
Basic UDI-DI	4538612020009M

Details of the system components:

No.	Device Name	Model	Type
1	DYNASCOPE 8000 Series DS-8400 System	DSC-8400	DSC-8410
2	Display Unit	LC-8000	LC-8016TC
3	Display Unit	LC-8000	LC-8018TC

List of Accessories for Class IIb medical device:

No.	Device Name	Model	Type
1	HS Adapter	HSA-80	HSA-80
2	HS Adapter	HSA-80	HSA-81
3	Multi Module	HM-800	HM-800
4	Multi Module	HM-800	HM-801
5	CO2 Gas Unit	HCP-810	HCP-810
6	GAS Unit I/F	HPD-810	HPD-810
7	BISx I/F Unit	HBX-800	HBX-800
8	Super Unit	HS-8000	HS-8312M
9	Super Unit	HS-8000	HS-8312N
10	SpO2 Module	HG-800	HG-810
11	SpO2 Module	HG-800	HG-820
12	Multiport Module	HP-800	HP-800
13	Recorder Unit	HR-800	HR-800
14	Input Box	IB-8000	IB-8004
15	Multigas Unit I/F	MGU-800	MGU-801P
16	Multigas Unit I/F	MGU-800	MGU-802
17	Multigas Unit I/F	MGU-810	MGU-811P
18	Multigas Unit I/F	MGU-810	MGU-812

**Appendix 2**

Medical Device description	
Device Name	Reusable Accessories for DS-8400
EMDN Code	Z1203020201 (MULTI-PARAMETER PATIENT BEDSIDE MONITORS)
Intended Purpose	<p>These are accessories to support DS-8400 or use to operate DS-8400. DS-8400 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 (SpO<sub>2</sub>), pulse rate, invasive blood pressure, non-invasive blood pressure, CO<sub>2</sub> concentration, O<sub>2</sub> concentration, cardiac output (CO), blood temperature and anesthetic gas concentration (including N<sub>2</sub>O, 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-23A04 RED: 063020D-17614
Basic UDI-DI	4538612020019P

Reusable Accessories for DS-8400 intended to be used in combination with DYNASCOPE 8000 Series DS-8400 System

No.	Device Name	Model	Type
1	Expansion Board	CC-80	CC-84
2	Lithium-Ion Battery Pack	BTO-005	-
3	Lower Trolley Unit for Monitor	OTO-13	-
4	GCX Attachment for Monitor	OAO-70A	-
5	Upper Trolley Unit for Monitor	OAO-8400	-
6	Cover Panel	OAO-45A	-
7	HS Attachment Spacer	OAO-46A	-
8	HS Rail Clamp	OAO-48A	-
9	HS Suspended Base	OAO-49A	-
10	HS Pole Clamp	OAO-50A	-
11	IB Clamp Base	OAO-51A	-
12	HS Fixing Base	OAO-52A	-
13	Storage Box for Trolley	OAO-91A	-
14	Mounting Bracket for Gas Unit/External Output Box	OAO-100A	-
15	TM XMTR Module HLX-801	HLX-801	-
16	IR Remote Control Unit	CF-820	CF-820
17	Recording Paper	OP050-02TDR	-
18	CF Card	FCF-128	-
19	CF Card	FCF-1000	-
20	SD Card	SD-1G	-
21	SD Card	SD-8G	-
22	SD Card	SD-16G	-
23	SD Card	FSD-8GA	-
24	CFast Card	FCS-64G	-
25	12-Lead Analysis Optional Software	DS-8400-12LA	-
26	External Output Box	CJO-C01Q-SJ0.3	-

**Appendix 2 (continued)**

No.	Device Name	Model	Type
27	Module Connection Cable	CJO-08SS0.3	-
28	Module Connection Cable	CJO-08SS1.5	-
29	Module Connection Cable	CJO-08SS3.5	-
30	Module Connection Cable	CJO-08SS5	-
31	Module Connection Cable	CJO-08SS10	-
32	Unit Connection Cable	CJO-09SS0.3	-
33	Unit Connection Cable	CJO-09SS1.5	-
34	Unit Connection Cable	CJO-09SS5	-
35	AUX Connection Cable	CJO-15RR0.65	-
36	AUX Connection Cable	CJO-15RR1.5	-
37	AUX Connection Cable	CJO-15RR3	-
38	AUX Connection Cable LEM	CJO-25TR0.36	-
39	AUX Connection Cable LEM	CJO-25TR0.65	-
40	AUX Connection Cable LEM	CJO-25TR1.5	-
41	AUX Connection Cable LEM	CJO-25TR2.7	-
42	3ch Analog Output Cable	CJO-26JJ0.5	-
43	3ch Analog Output Cable	CJO-26JJ2.7	-
44	Earth wire	CE-01A	-
45	Earth wire	CE-12	-
46	Ethernet Branch Cable	CJ-522A	-
47	Ethernet Branch Cable	CJ-522B	-
48	Ethernet Branch Cable	CJ-522C	-
49	Ethernet Branch Cable	CJ-522D	-
50	Ethernet Branch Cable	CJ-522E	-
51	Display Unit Connection Cable	CJ-731B	-
52	Display Unit Connection Cable	CJ-731C	-
53	Display Unit Connection Cable	CJ-731D	-
54	BIS Monitor interface cable	CJO-03RS4	-
55	Vigilance connection cable	CJO-04RS4	-
56	Relay Cable	CJ-502	-
57	RS-232C Cross cable	CJ-725	-
58	Relay Cable (Straight)	CJ-726	-
59	Relay Cable (Straight)	CJ-727	-
60	SV-300 interface cable	CJ-401RI-70SV3	-
61	Relay Cable	CJ-402RI-70SVi	-
62	PB700/800 serial interface cable	CJ-403RI-70PB	-
63	Vigilance connection cable	CJ-406RI-70Vigi	-
64	BIS Monitor interface cable	CJ-407RI-70BIS	-
65	PiCCO Connection Cable (Serial)	CJO-18RS5	-
66	PiCCO Connection Cable (Status II)	CJO-19RS5	-
67	Serial Converter Cable	CJ-756	-
68	GE Anesthesia System Connection Cable	CJO-31RS5	-
69	Power Cable	CS-18	-
70	Power Cable	CS-33	-

**Appendix 2 (continued)**

No.	Device Name	Model	Type
71	Power Cable	CS-55-ST	-
72	Power Cable	CS-55-RA	-
73	Power Cable	CS-56-ST	-
74	Power Cable	CS-57-ST	-
75	Power Cable	CS-57-RA	-
76	Power Cable	CS-58-ST	-
77	Power Cable	CS-59-ST	-
78	Trolley(L)	OTO-16L	-
79	Mounting Bracket for MGU-800	OAO-1006A	-
80	Balancer for Trolley	OAO-1011A	-

**ECG Accessory**

No.	Device Name	Model	Type
81	ECG relay cable	CIO-05CTP-3NU	-
82	ECG relay cable	CIO-05CTP-4NU	-
83	ECG relay cable	CIO-05CTP-5NU	-
84	ECG relay cable	CIO-05CTP-10NU	-
85	ECG relay cable	CIO-08CTP-3EU	-
86	ECG relay cable	CIO-08CTP-5EU	-
87	Patient Cable Adapter	CIZ-173DIN-3-U	-
88	Patient Cable Adapter	CIZ-173DIN-5-U	-
89	Patient Cable Adapter	CIZ-173DIN-C-U	-

**Blood Pressure Accessory**

No.	Device Name	Model	Type
90	BP Relay Cable	CJO-P01B-SB3.6	-
91	2ch BP Relay Cable	CJO-P01B-DB0.8	-
92	2ch BP Relay Cable	CJO-P01B-DB4.3	-
93	2ch BP Conversion Cable	CJO-P01B-DJ0.5	-

**Temperature Accessory**

No.	Device Name	Model	Type
94	2ch Temperature Relay Cable	CJO-P01T-DA0.5	-
95	2ch Temperature Relay Cable	CJO-P01T-DA4.0	-

**CO Accessory**

No.	Device Name	Model	Type
96	Catheter Relay Cable	CJO-P01C-C2.4	-
97	Flow-Through Sensor Relay Cable	CJO-P01C-F2.4	-
98	In-Line Sensor Relay Cable	CJO-P01C-L2.4	-
99	Injectate Probe Relay Cable	CJO-P01C-T2.4	-

**NIBP Accessory**

No.	Device Name	Model	Type
100	Air Hose	OA-80APS1.5-S	-
101	Air Hose	OA-80APS3.5-S	-
102	Air Hose	OA-80NE1.5-S	-
103	Air Hose	OA-80NE3.5-S	-