

## 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 1000 Series DS-1200 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 checked="" type="checkbox"/> RE Directive (2014/53/EU)
	Reusable Accessories for DS-1200 *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 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 : 19 December 2022

  
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 Takashi Nomura  
 General Manager  
 Quality Assurance Department

**Appendix 1**

<b>Medical Device description</b>	
Device Name	DYNASCOPE 1000 Series DS-1200 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	Annex II of Directive 2014/53/EU
Technical Document	MDR / RoHS: 063150H-24717 RED: 063150D-24B09
Basic UDI-DI	4538612020009M

Details of the system components:

No.	Device Name	Model	Type
1	DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200N
2	DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200NR
3	DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200NT
4	DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200NRT
5	DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200M
6	DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200MR
7	DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200MT
8	DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200MRT

List of Accessories for Class IIb medical device:

No.	Device Name	Model	Type
1	CO2 Gas Module	HC-110	HC-110
2	Gas Unit I/F Module	HC-120	HC-120
3	Multi Gas Module	MG-110	MG-110
4	Multi Gas Module S	MG-120	MG-120
5	Multi Module	HM-800	HM-800
6	SpO2 Module	HG-800	HG-810
7	SpO2 Module	HG-800	HG-820
8	Multiport Module	HP-800	HP-800

**Appendix 2**

<b>Medical Device description</b>	
Device Name	Reusable Accessories for DS-1200
EMDN Code	Z1203020201 (MULTI-PARAMETER PATIENT BEDSIDE MONITORS)
Intended Purpose	<p>These are accessories to support DS-1200 or use to operate DS-1200. DS-1200 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	N/A
Technical Document	MDR / RoHS: 063150H-24717 RED: N/A
Basic UDI-DI	4538612020019P

Reusable Accessories for DS-1200 intended to be used in combination with DYNASCOPE 1000 Series DS-1200 System.

No.	Device Name	Model	Type
1	Lithium-ion Battery Pack	BTO-005	-
2	Storage Box for Trolley	OAO-91A	-
3	Lower Trolley Unit for Monitor	OTO-13	-
4	GCX Attachment for Monitor	OAO-70A	-
5	Upper Trolley Unit for Monitor	OAO-8400	-
6	Trolley (S)	OTO-16S	-
7	Balancer for Trolley	OAO-1011A	-
8	Trolley (L)	OTO-16L	-
9	Recording Paper	OP050-02TDR	-
10	Earth wire	CE-01A	-
11	PiCCO Connection Cable (Serial)	CJO-18RS5	-
12	PiCCO Connection Cable (Status II)	CJO-19RS5	-
13	3ch Analog Output Cable	CJO-26JJ0.5	-
14	3ch Analog Output Cable	CJO-26JJ2.7	-
15	BISx IF Cable	CJO-29TR0.4	-
16	SD Card	FSD-32G	-
17	IR Remote Control Unit	CF-800	CF-820
18	Ethernet Branch Cable	CJ-522A	-
19	Ethernet Branch Cable	CJ-522B	-
20	Ethernet Branch Cable	CJ-522C	-
21	Ethernet Branch Cable	CJ-522D	-
22	Ethernet Branch Cable	CJ-522E	-
23	BIS Monitor interface cable	CJO-03RS4	-
24	Vigilance connection cable	CJO-04RS4	-

**Appendix 2 (continued)**

No.	Device Name	Model	Type
25	Relay Cable	CJ-502	-
26	RS-232C Cross cable	CJ-725	-
27	Relay Cable (Straight)	CJ-726	-
28	SV-300 interface cable	CJ-401RI-70SV3	-
29	Relay Cable	CJ-402RI-70SVi	-
30	PB700/800 serial interface cable	CJ-403RI-70PB	-
31	Vigilance connection cable	CJ-406RI-70Vigi	-
32	BIS Monitor interface cable	CJ-407RI-70BIS	-
33	Serial Converter Cable	CJ-756	-
34	Power Cable	CS-18	-
35	Power Cable	CS-33	-
36	Power Cable	CS-55-ST	-
37	Power Cable	CS-55-RA	-
38	Power Cable	CS-56-ST	-
39	Power Cable	CS-57-ST	-
40	Power Cable	CS-57-RA	-
41	Power Cable	CS-58-ST	-
42	Power Cable	CS-59-ST	-

**ECG Accessory**

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

**Blood Pressure Accessory**

No.	Device Name	Model	Type
52	BP Relay Cable	CJO-P01B-SB3.6	-
53	2ch BP Relay Cable	CJO-P01B-DB0.8	-
54	2ch BP Relay Cable	CJO-P01B-DB4.3	-
55	2ch BP Conversion Cable	CJO-P01B-DJ0.5	-

**Temperature Accessory**

No.	Device Name	Model	Type
56	2ch Temperature Relay Cable	CJO-P01T-DA0.5	-
57	2ch Temperature Relay Cable	CJO-P01T-DA4.0	-

**CO Accessory**

No.	Device Name	Model	Type
58	Catheter Relay Cable	CJO-P01C-C2.4	-
59	Flow-Through Sensor Relay Cable	CJO-P01C-F2.4	-
60	In-Line Sensor Relay Cable	CJO-P01C-L2.4	-
61	Injectate Probe Relay Cable	CJO-P01C-T2.4	-



**Appendix 2 (continued)**

**NIBP Accessory**

No.	Device Name	Model	Type
62	Air Hose	OA-80APS1.5-S	-
63	Air Hose	OA-80APS3.5-S	-
64	Air Hose	OA-80NE1.5-S	-
65	Air Hose	OA-80NE3.5-S	-
66	All Purpose Blood Pressure Cuff	CUF-1000-XS	-
67	All Purpose Blood Pressure Cuff	CUF-1000-S	-
68	All Purpose Blood Pressure Cuff	CUF-1000-M	-
69	All Purpose Blood Pressure Cuff	CUF-1000-L	-
70	All Purpose Blood Pressure Cuff	CUF-1000-XL	-