

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.
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SRN	JP-MF-000008253
Location of Design 1	Fukuda Denshi Co., Ltd. 2-35-8 Hongo, Bunkyo-ku, Tokyo 113-8420 Japan
Location of Design 2	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 (Device Family)	Measuring and Monitoring Device for Vital Signs	
Device Name	DYNASCOPE 8000 Series DS-8007 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 DYNASCOPE 8000 Series DS-8007 System *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)	
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Appendix 1

Medical Device description	
Device Name	DYNASCOPE 8000 Series DS-8007 System
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-22704 RED : N/A

Details of the system components:

1. Main unit

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.

No.	Device Name	Model	Type	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
1.	DYNASCOPE 8000 Series DS-8007 System	DS-8007	DS-8007N	Z1203020201	33586	4538612020009M	X	-
2.	DYNASCOPE 8000 Series DS-8007 System	DS-8007	DS-8007M	Z1203020201	33586	4538612020009M	X	-

2. List of Class IIb Accessories:

Intended Purpose: These are the accessories to be used together with DYNASCOPE 8000 Series DS-8007 System to enable it to be used in accordance with its intended purpose.

*Refer to the following list for further details.

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
1.	AC Unit	DSA-81	DSA-81	DSA-81 is AC power unit of DS-8007 system. This unit has serial communication port and DS-LAN interface.	Z12030 20280	33586	4538612020009M	X	-
2.	DS-8007 Adapter	DSA-82	DSA-82	DSA-82 is an adapter used to connect the Super Unit (HS-8000 series) or/and the patient monitor (DS-8007 series) with the host monitor.	Z12030 20280	33586	4538612020009M	X	-
3.	BISx I/F Unit	HBX-800	HBX-800	HBX-800 is an interface unit between the AUX connector of the HS-8312N/HS-8312M (or other device which the HBX-800 is connected to) and the BISx Module to measure the BIS, SQI, SR and EMG.	Z12030 20280	33586	4538612020009M	X	-
4.	CO2 Gas Unit	HCP-810	HCP-810	HCP-810 is a CO ₂ concentration measurement unit. By connecting this unit to the main unit, carbon dioxide (CO ₂) concentration can be measured in sidestream method.	Z12030 20280	33586	4538612020009M	X	-
5.	CO2 Gas Unit	HCP-820	HCP-820	HCP-820 is a CO ₂ concentration measurement unit. By connecting this unit to the main unit, carbon dioxide (CO ₂) concentration can be measured in sidestream method.	Z12030 20280	33586	4538612020009M	X	-
6.	Gas Unit I/F	HPD-810	HPD-810	HPD-810 is an interface unit between the AUX connector of the main unit and the Capnostat 5 (mainstream CO ₂ sensor) to measure the CO ₂ concentration.	Z12030 20280	33586	4538612020009M	X	-
7.	Gas Unit I/F	HPD-820	HPD-820	HPD-820 is an interface unit between the Gas Unit connector of the DS-8007 Patient Monitor System and the Capnostat 5 (mainstream CO ₂ sensor) to measure the CO ₂ concentration.	Z12030 20280	33586	4538612020009M	X	-
8.	Recorder Unit	HR-800	HR-800	HR-800 is used to print the waveforms, numeric data and graphic trend monitored on the main unit.	Z12030 20280	33586	4538612020009M	X	-

Appendix 2

Medical Device description	
Device Name	Reusable Accessories for DYNASCOPE 8000 Series DS-8007 System
Device Class	Class I-sc (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-22704 RED : 063020D-17614

List of Class I-sc Reusable Accessories for DYNASCOPE 8000 Series DS-8007 System.

Intended Purpose: These are the accessories to be used together with DYNASCOPE 8000 Series DS-8007 System to enable it to be used in accordance with its intended purpose.

*Refer to the following list for further details.

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
1.	TM XMTR Module HLX-801	HLX-801	-	HLX-801 is a transmitter module to wirelessly transmit vital signal waveforms and numeric data which are monitored on the DS-8000 series bedside monitors.	Z12030 20280	33586	4538612020019P	X	X
2.	Earth wire	CE-01A	-	CE-01A is a cable for grounding the device. It is used to safely route the electric current generated in each part of the device to the ground, to prevent patients and operators from receiving electric shocks.	V9099	47487	4538612020019P	X	-
3.	Power Cable	CS-18	-	CS-18 is AC power cable for main unit.	V9099	45804	4538612020019P	X	-
4.	Power Cable	CS-55-ST	-	CS-55-ST is AC power cable for main unit.	V9099	45804	4538612020019P	X	-
5.	Power Cable	CS-55-RA	-	CS-55-RA is AC power cable for main unit.	V9099	45804	4538612020019P	X	-
6.	Power Cable	CS-56-ST	-	CS-56-ST is AC power cable for main unit.	V9099	45804	4538612020019P	X	-
7.	Power Cable	CS-57-ST	-	CS-57-ST is AC power cable for main unit.	V9099	45804	4538612020019P	X	-
8.	Power Cable	CS-57-RA	-	CS-57-RA is AC power cable for main unit.	V9099	45804	4538612020019P	X	-
9.	Power Cable	CS-58-ST	-	CS-58-ST is AC power cable for main unit.	V9099	45804	4538612020019P	X	-
10.	Power Cable	CS-59-ST	-	CS-59-ST is AC power cable for main unit.	V9099	45804	4538612020019P	X	-

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
11.	SD Card	SD-16G	-	This device is a SD type memory card to be used for the storage of patient information and measurement data.	V9099	62804	4538612020019P	X	-
12.	SD Card	FSD-8GA	-	This device is a SD type memory card to be used for the storage of patient information and measurement data.	V9099	62804	4538612020019P	X	-
13.	Rechargeable Lithium-ion Battery Pack	BTO-008	-	BTO-008 is a rechargeable battery for the main unit.	V9099	36534	4538612020019P	X	-
14.	Recording Paper	OP050-02TDR	-	OP050-02TDR is a roll-type thermal paper used for printing and recording waveforms and measurement values.	Z12030 20285	16754	4538612020019P	-	-
15.	12-Lead Analysis Optional Software	DS-8007-12LA	-	DS-8007-12LA is an optional software for enabling the 12-lead analysis function on DS-8007 system.	Z12030 20282	33586	4538612020019P	-	-
16.	GCX Attachment for Monitor	OAO-70A	-	OAO-70A is used for mounting the patient monitor on the GCX arm.	Z12030 20280	61434	4538612020019P	-	-
17.	Bed Mount for Patient Monitor	OAO-102A	-	OAO-102A is an attachment bracket used to mount the DS-8007 Patient Monitor to the bedside rail.	Z12030 20280	36178	4538612020019P	-	-
18.	AUX Unit Mounting Bracket	OAO-103A	-	OAO-103A is an attachment bracket used to mount the CO2 Gas Unit (HCP-810), Gas Unit I/F (HPD-810) or BISx I/F Unit (HBX-800) to the DS-8007 Patient Monitor.	Z12030 20280	61434	4538612020019P	-	-
19.	Countertop for Patient Monitor	OAO-104A	-	OAO-104A is an attachment bracket used to mount the patient monitor to a shelf.	Z12030 20280	61434	4538612020019P	-	-
20.	Mounting Bracket for Pole Clamp	OAO-105A	-	OAO-105A is an attachment bracket used to mount the patient monitor to a pole (ϕ 19 mm to 38 mm).	Z12030 20280	41893	4538612020019P	-	-
21.	HLX Holder for DSA-81	OAO-111A	-	OAO-111A is used for fixing the TM XMTR Module HLX-801 to the AC Unit (DSA-81).	Z12030 20280	61434	4538612020019P	-	-
22.	Mounting Bracket for HR-800	OAO-1003A	-	OAO-1003A is a bracket to attach the recorder unit (HR-800) to the trolley.	Z12030 20280	61434	4538612020019P	-	-
23.	Trolley (S)	OTO-16S	-	OTO-16S is a wheeled cart used for transporting the vital sign monitors and accessories.	Z12030 20280	40596	4538612020019P	-	-

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
24.	SV-300 interface cable	CJ-401RI-70SV3	-	CJ-401RI-70SV3 is the external device connection cable used to connect the main unit and the external device such as a ventilator for communication.	Z12030 20280	47487	4538612020019P	X	-
25.	Relay Cable	CJ-402RI-70SVI	-	CJ-402RI-70SVI is the external device connection cable used to connect the main unit and the external device such as a ventilator for communication.	Z12030 20280	47487	4538612020019P	X	-
26.	PB700/800 serial interface cable	CJ-403RI-70PB	-	CJ-403RI-70PB is the external device connection cable used to connect the main unit and the external device such as a ventilator for communication.	Z12030 20280	47487	4538612020019P	X	-
27.	BIS Monitor interface cable	CJ-407RI-70BIS	-	CJ-407RI-70BIS is the external device connection cable used to connect the main unit and the external device such as BIS monitor for communication.	Z12030 20280	47487	4538612020019P	X	-
28.	Ethernet Branch Cable	CJ-522A	-	CJ-522 series is the connection cable used to connect the main unit and the ethernet hub for DS-LAN communication.	Z12030 20280	47487	4538612020019P	X	-
29.	Ethernet Branch Cable	CJ-522B	-	CJ-522 series is the connection cable used to connect the main unit and the ethernet hub for DS-LAN communication.	Z12030 20280	47487	4538612020019P	X	-
30.	Ethernet Branch Cable	CJ-522C	-	CJ-522 series is the connection cable used to connect the main unit and the ethernet hub for DS-LAN communication.	Z12030 20280	47487	4538612020019P	X	-
31.	Ethernet Branch Cable	CJ-522D	-	CJ-522 series is the connection cable used to connect the main unit and the ethernet hub for DS-LAN communication.	Z12030 20280	47487	4538612020019P	X	-
32.	Ethernet Branch Cable	CJ-522E	-	CJ-522 series is the connection cable used to connect the main unit and the ethernet hub for DS-LAN communication.	Z12030 20280	47487	4538612020019P	X	-
33.	RS-232C Cross cable	CJ-725	-	CJ-725 is the external device connection cable used to connect the main unit and the external device for serial communication.	Z12030 20280	47487	4538612020019P	X	-
34.	Serial Converter Cable	CJ-756	-	CJ-756 is the external device connection cable used to connect the main unit and the external device for serial communication.	Z12030 20280	47487	4538612020019P	X	-

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
35.	BIS Monitor interface cable	CJO-03RS4	-	CJO-03RS4 is the external device connection cable used to connect the main unit and the external device such as a BIS monitor for communication.	Z12030 20280	47487	4538612020019P	X	-
36.	Module Connection Cable	CJO-08SS0.3	-	CJO-08SS series is the connection cable used to connect the main unit and various measurement modules for communication.	Z12030 20280	47487	4538612020019P	X	-
37.	Module Connection Cable	CJO-08SS1.5	-	CJO-08SS series is the connection cable used to connect the main unit and various measurement modules for communication.	Z12030 20280	47487	4538612020019P	X	-
38.	Module Connection Cable	CJO-08SS3.5	-	CJO-08SS series is the connection cable used to connect the main unit and various measurement modules for communication.	Z12030 20280	47487	4538612020019P	X	-
39.	Module Connection Cable	CJO-08SS5	-	CJO-08SS series is the connection cable used to connect the main unit and various measurement modules for communication.	Z12030 20280	47487	4538612020019P	X	-
40.	Module Connection Cable	CJO-08SS10	-	CJO-08SS series is the connection cable used to connect the main unit and various measurement modules for communication.	Z12030 20280	47487	4538612020019P	X	-
41.	Unit Connection Cable	CJO-09SS0.3	-	CJO-09SS series is the connection cable used to connect the main unit and various units for communication.	Z12030 20280	47487	4538612020019P	X	-
42.	Unit Connection Cable	CJO-09SS1.5	-	CJO-09SS series is the connection cable used to connect the main unit and various units for communication.	Z12030 20280	47487	4538612020019P	X	-
43.	Unit Connection Cable	CJO-09SS5	-	CJO-09SS series is the connection cable used to connect the main unit and various units for communication.	Z12030 20280	47487	4538612020019P	X	-
44.	AUX Connection Cable LEM	CJO-25TR0.65	-	CJO-25TR series is the connection cable used to connect the AUX connector and the measurement unit for communication.	Z12030 20280	47487	4538612020019P	X	-
45.	AUX Connection Cable LEM	CJO-25TR1.5	-	CJO-25TR series is the connection cable used to connect the AUX connector and the measurement unit for communication.	Z12030 20280	47487	4538612020019P	X	-
46.	AUX Connection Cable LEM	CJO-25TR2.7	-	CJO-25TR series is the connection cable used to connect the AUX connector and the measurement unit for communication.	Z12030 20280	47487	4538612020019P	X	-

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
47.	3ch Analog Output Cable	CJO-26JJ0.5	-	CJO-26JJ series is the connection cable used to output the measured waveform to the external device.	Z12030 20280	47487	4538612020019P	X	-
48.	3ch Analog Output Cable	CJO-26JJ2.7	-	CJO-26JJ series is the connection cable used to output the measured waveform to the external device.	Z12030 20280	47487	4538612020019P	X	-
49.	ECG Relay Cable	CIO-05CTP-3NU	-	A noninvasive device intended to be used to conduct electrical signals from a patient's heart, via an electrode attached to the surface of the chest to an electrocardiograph (ECG) machine or a patient monitoring system. This is a reusable device, and a cable with connector. This device cannot be used in MR environment.	Z12030 20280	47487	4538612020019P	X	-
50.	ECG Relay Cable	CIO-05CTP-4NU	-	A noninvasive device intended to be used to conduct electrical signals from a patient's heart, via an electrode attached to the surface of the chest to an electrocardiograph (ECG) machine or a patient monitoring system. This is a reusable device, and a cable with connector. This device cannot be used in MR environment.	Z12030 20280	47487	4538612020019P	X	-
51.	ECG Relay Cable	CIO-05CTP-5NU	-	A noninvasive device intended to be used to conduct electrical signals from a patient's heart, via an electrode attached to the surface of the chest to an electrocardiograph (ECG) machine or a patient monitoring system. This is a reusable device, and a cable with connector. This device cannot be used in MR environment.	Z12030 20280	47487	4538612020019P	X	-
52.	ECG Relay Cable	CIO-05CTP-10NU	-	A noninvasive devices intended to be used to conduct electrical signals from a patient's heart, via an electrode attached to the surface of the chest to an electrocardiograph (ECG) machine or a patient monitoring system. This is a reusable device, and a cable with connector. This device cannot be used in MR environment.	Z12030 20280	47487	4538612020019P	X	-
53.	ECG Relay Cable	CIO-08CTP-3EU	-	CIO-08CTP series is an ECG relay cable intended to be used during electrosurgery to minimize ESU interference.	Z12030 20280	47487	4538612020019P	X	-

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
54.	ECG Relay Cable	CIO-08CTP-5EU	-	CIO-08CTP series is an ECG relay cable intended to be used during electrosurgery to minimize ESU interference.	Z12030 20280	47487	4538612020019P	X	-
55.	Patient Cable Adapter	CIZ-173DIN-3-U	-	CIZ-173DIN series is an ECG patient cable adapter designed to connect the electrocardiograph to electrodes with pin plug.	Z12030 20280	47487	4538612020019P	X	-
56.	Patient Cable Adapter	CIZ-173DIN-5-U	-	CIZ-173DIN series is an ECG patient cable adapter designed to connect the electrocardiograph to electrodes with pin plug.	Z12030 20280	47487	4538612020019P	X	-
57.	Patient Cable Adapter	CIZ-173DIN-C-U	-	CIZ-173DIN series is an ECG patient cable adapter designed to connect the electrocardiograph to electrodes with pin plug.	Z12030 20280	47487	4538612020019P	X	-
58.	2ch BP Relay cable	CJO-P01B-DB0.8	-	CJO-P01B-DB series is a relay cable for connecting the multi-parameter connector of a patient monitor to a two-channel blood pressure transducer.	Z12030 20280	47487	4538612020019P	X	-
59.	2ch BP Relay cable	CJO-P01B-DB4.3	-	CJO-P01B-DB series is a relay cable for connecting the multi-parameter connector of a patient monitor to a two-channel blood pressure transducer.	Z12030 20280	47487	4538612020019P	X	-
60.	2ch BP Conversion Cable	CJO-P01B-DJ0.5	-	CJO-P01B-DJ0.5 is a cable for converting a two-channel blood pressure transducer to be connected to the multi-parameter connector of a patient monitor.	Z12030 20280	47487	4538612020019P	X	-
61.	BP Relay cable	CJO-P01B-SB3.6	-	CJO-P01B-SB3.6 is a relay cable for connecting the multi-parameter connector of a patient monitor to a one-channel blood pressure transducer.	Z12030 20280	47487	4538612020019P	X	-
62.	Air Hose	OA-80APS1.5-S	-	OA-80 series is intended to be used to connect the NIBP cuff to the main device.	Z12030 20280	61228	4538612020019P	X	-
63.	Air Hose	OA-80APS3.5-S	-	OA-80 series is intended to be used to connect the NIBP cuff to the main device.	Z12030 20280	61228	4538612020019P	X	-
64.	Air Hose	OA-80NE1.5-S	-	OA-80 series is intended to be used to connect the NIBP cuff to the main device.	Z12030 20280	61228	4538612020019P	X	-
65.	Air Hose	OA-80NE3.5-S	-	OA-80 series is intended to be used to connect the NIBP cuff to the main device.	Z12030 20280	61228	4538612020019P	X	-

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
66.	2ch Temperature Relay Cable	CJO-P01T-DA0.5	-	CJO-P01T-DA series is a relay cable for connecting the multi-parameter connector of a patient monitor to a two-channel temperature probe.	Z12030 20280	47487	4538612020019P	X	-
67.	2ch Temperature Relay Cable	CJO-P01T-DA4.0	-	CJO-P01T-DA series is a relay cable for connecting the multi-parameter connector of a patient monitor to a two-channel temperature probe.	Z12030 20280	47487	4538612020019P	X	-
68.	Catheter Relay Cable	CJO-P01C-C2.4	-	CJO-P01C-C2.4 is a relay cable for connecting the multi-parameter connector of a patient monitor to a thermodilution catheter with 0°C/24°C temperature method.	Z12030 20280	47487	4538612020019P	X	-
69.	Flow-Through Sensor Relay Cable	CJO-P01C-F2.4	-	CJO-P01C-F2.4 is a relay cable for connecting the multi-parameter connector of a patient monitor to a thermodilution catheter with flow-through sensor.	Z12030 20280	47487	4538612020019P	X	-
70.	In-Line Sensor Relay Cable	CJO-P01C-L2.4	-	CJO-P01C-L2.4 is a relay cable for connecting the multi-parameter connector of a patient monitor to a thermodilution catheter with in-line sensor.	Z12030 20280	47487	4538612020019P	X	-
71.	Injectate Probe Relay Cable	CJO-P01C-T2.4	-	CJO-P01C-T2.4 is a relay cable for connecting the multi-parameter connector of a patient monitor to a thermodilution catheter with injectate temperature probe.	Z12030 20280	47487	4538612020019P	X	-