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 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. Shiroi Factory 305-1 Naka, Shiroi-shi, Chiba 270-1495 Japan

Medical Device		
Product Category (Device Family)	Measuring and Monitoring Device for Vital Signs	
Device Name	DYNASCOPE 1000 Series BDS-1001 System *Refer to the Appendix 1 for details.	☒ MDR ((EU)2017/745) ☒ RoHS Directive (2011/65/EU) ☒ RE Directive (2014/53/EU)
	Reusable Accessories for DYNASCOPE 1000 Series BDS-1001 System *Refer to the Appendix 2 for details.	☒ MDR ((EU)2017/745) ☒ RoHS Directive (2011/65/EU) ☐ 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 B.V.
Address	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
SRN	NL-AR-000000116

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Yuki MITOBE, PRRC
Senior Manager
Quality Assurance Head Office

Appendix 1

Medical Device description	
Device Name	DYNASCOPE 1000 Series BDS-1001 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	Annex II of Directive 2014/53/EU
Technical Document	MDR / RoHS : 063150H-24903 RED : 063150D-25901

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, arterial oxygen saturation (SpO_2), pulse rate, non-invasive blood pressure, and CO_2 concentration.

No.	Device Name	Model	Type	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
1.	DYNASCOPE 1000 Series BDS-1001 System	BDS-1001	BDS-1001ENT	Z1203020201	33586	4538612020009M	X	X
2.	DYNASCOPE 1000 Series BDS-1001 System	BDS-1001	BDS-1001EN	Z1203020201	33586	4538612020009M	X	-
3.	DYNASCOPE 1000 Series BDS-1001 System	BDS-1001	BDS-1001NT	Z1203020201	33586	4538612020009M	X	X
4.	DYNASCOPE 1000 Series BDS-1001 System	BDS-1001	BDS-1001N	Z1203020201	33586	4538612020009M	X	-
5.	DYNASCOPE 1000 Series BDS-1001 System	BDS-1001	BDS-1001EMT	Z1203020201	33586	4538612020009M	X	X
6.	DYNASCOPE 1000 Series BDS-1001 System	BDS-1001	BDS-1001EM	Z1203020201	33586	4538612020009M	X	-
7.	DYNASCOPE 1000 Series BDS-1001 System	BDS-1001	BDS-1001MT	Z1203020201	33586	4538612020009M	X	X
8.	DYNASCOPE 1000 Series BDS-1001 System	BDS-1001	BDS-1001M	Z1203020201	33586	4538612020009M	X	-

2. List of Class IIb Accessories:

Intended Purpose: These are the accessories to be used together with DYNASCOPE 1000 Series BDS-1001 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.	CO2 Gas Unit	HCP-110	HCP-110	HCP-110 is a CO2 Gas Unit which measures CO_2 concentration by connecting to the gas unit connector on the BDS-1001 system.	Z1203020280	33586	4538612020009M	X	-
2.	Recorder Unit	HR-110	HR-110	HR-110 Recorder Unit is used to record waveforms, numeric data and graphic trend monitored on the BDS-1001 system.	Z1203020280	33586	4538612020009M	X	-

Appendix 2

Medical Device description	
Device Name	Reusable Accessories for DYNASCOPE 1000 Series BDS-1001 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	N/A
Technical Document	MDR / RoHS : 063150H-24903 RED : N/A

List of Class I-sc Reusable Accessories for DYNASCOPE 1000 Series BDS-1001 System.

Intended Purpose: These are the accessories to be used together with DYNASCOPE 1000 Series BDS-1001 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.	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	-
2.	Power Cable	CS-18	-	CS-18 is AC power cable for main unit.	V9099	45804	4538612020019P	X	-
3.	Power Cable	CS-33	-	CS-33 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	-
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	-

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
12.	Rechargeable Lithium-ion Battery Pack	BTO-008	-	BTO-008 is a rechargeable battery for the main unit.	V9099	36534	4538612020019P	X	-
13.	Recording Paper	OP050-02TDR	-	OP050-02TDR is a roll-type thermal paper used for printing and recording waveforms and measurement values.	Z1203020285	16754	4538612020019P	-	-
14.	GCX Attachment for Monitor	OAO-116A	-	OAO-116A is used for mounting the patient monitor on the GCX arm.	Z1203020280	61434	4538612020019P	-	-
15.	Trolley Attachment for Monitor	OAO-118A	-	OAO-118A is used for mounting the patient monitor on the trolley.	Z1203020280	61434	4538612020019P	-	-
16.	Bed Mount for Monitor	OAO-119A	-	OAO-119A is used for mounting the patient monitor on a bed rail.	Z1203020280	36178	4538612020019P	-	-
17.	Detachable Attachment for Patient Monitor	OAO-1000	-	OAO-1000 is secured on the top panel of the trolley (OTO-16S) to attach/ detach a monitor.	Z1203020280	61434	4538612020019P	-	-
18.	Trolley (S)	OTO-16S	-	OTO-16S is a wheeled cart used for transporting the vital sign monitors and accessories.	Z1203020280	40596	4538612020019P	-	-
19.	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.	Z1203020280	47487	4538612020019P	X	-
20.	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.	Z1203020280	47487	4538612020019P	X	-
21.	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.	Z1203020280	47487	4538612020019P	X	-
22.	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.	Z1203020280	47487	4538612020019P	X	-

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
23.	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.	Z120302 0280	47487	4538612020019P	X	-
24.	ECG Relay Cable	CIO-08CTP-3EU	-	CIO-08CTP series is an ECG relay cable intended to be used during electrosurgery to minimize ESU interference.	Z120302 0280	47487	4538612020019P	X	-
25.	ECG Relay Cable	CIO-08CTP-5EU	-	CIO-08CTP series is an ECG relay cable intended to be used during electrosurgery to minimize ESU interference.	Z120302 0280	47487	4538612020019P	X	-
26.	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.	Z120302 0280	47487	4538612020019P	X	-
27.	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.	Z120302 0280	47487	4538612020019P	X	-
28.	Air Hose	OA-80APS1.5-S	-	OA-80 series is intended to be used to connect the NIBP cuff to the main device.	Z120302 0280	61228	4538612020019P	X	-
29.	Air Hose	OA-80APS3.5-S	-	OA-80 series is intended to be used to connect the NIBP cuff to the main device.	Z120302 0280	61228	4538612020019P	X	-
30.	Air Hose	OA-80NE1.5-S	-	OA-80 series is intended to be used to connect the NIBP cuff to the main device.	Z120302 0280	61228	4538612020019P	X	-
31.	Air Hose	OA-80NE3.5-S	-	OA-80 series is intended to be used to connect the NIBP cuff to the main device.	Z120302 0280	61228	4538612020019P	X	-
32.	All Purpose Blood Pressure Cuff	CUF-1000-XS	-	CUF-1000 series is a cuff for NIBP measurement equipment manufactured by Fukuda Denshi. It is intended to be used on the arm and thigh.	Z120302 0280	34978	4538612020019P	-	-
33.	All Purpose Blood Pressure Cuff	CUF-1000-S	-	CUF-1000 series is a cuff for NIBP measurement equipment manufactured by Fukuda Denshi. It is intended to be used on the arm and thigh.	Z120302 0280	34978	4538612020019P	-	-
34.	All Purpose Blood Pressure Cuff	CUF-1000-M	-	CUF-1000 series is a cuff for NIBP measurement equipment manufactured by Fukuda Denshi. It is intended to be used on the arm and thigh.	'Z120302 0280	34978	4538612020019P	-	-

No.	Device Name	Model	Type	Intended Purpose	EMDN Code	GMDN Code	Basic UDI-DI	RoHS	RE
35.	All Purpose Blood Pressure Cuff	CUF-1000-L	-	CUF-1000 series is a cuff for NIBP measurement equipment manufactured by Fukuda Denshi. It is intended to be used on the arm and thigh.	Z1203020280	34978	4538612020019P	-	-
36.	All Purpose Blood Pressure Cuff	CUF-1000-XL	-	CUF-1000 series is a cuff for NIBP measurement equipment manufactured by Fukuda Denshi. It is intended to be used on the arm and thigh.	Z1203020280	34978	4538612020019P	-	-