Declaration of Conformity

We declare under our sole responsibility that the following product to which this declaration relates is in conformity with the standards or other normative documents under the provisions of Medical Devices Regulation (EU) 2017/745 and RoHS Directive 2011/65/EU.

Product Category:	Measuring and Monitoring Device for Vital Signs
Device Name:	DYNASCOPE 1000 Series DS-1200 System (Refer to the Appendix 1 for the details of the system components)
Classification:	Class IIb Rule 10, Annex VIII of Medical Devices Regulation (EU) 2017/745
Basic UDI-DI:	4538612020009M
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).
EEE Categories:	8 Annex I of RoHS Directive 2011/65/EU
Manufacturer:	Fukuda Denshi Co., Ltd. 3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
SRN:	JP-MF-000008253
European Authorized Representative:	Emergo Europe Prinsessegracht 20, 2514 AP The Hague, The Netherlands
SRN:	NL-AR-000000116
Applied Annex:	Annex IX Chapter I and III of Medical Devices Regulation (EU) 2017/745
Notified Body:	BSI Group The Netherlands B.V. (2797) Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Certificate No.:	MDR 743406 Note: BSI's CE Certificate covers only Medical Devices Regulation (EU) 2017/745 Class IIa and IIb, but not RoHS Directive 2011/65/EU.
Accessories:	See Appendix 2
Technical Documents:	No. 063150H-24717

We declare under our sole responsibility that the following product to which this declaration relates is in conformity with the standards or other normative documents under the provisions of RE Directive 2014/53/EU.

Product Category:	Measuring and Monitoring Device for Vital Signs
Device Name:	DYNASCOPE 1000 Series DS-1200 System
Model:	DS-1200
Type:	DS-1200NT, DS-1200NRT, DS-1200MT, DS-1200MRT
Manufacturer:	Fukuda Denshi Co., Ltd. 3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
Location of design:	Fukuda Denshi Co., Ltd. Hongo Office 2-35-8 Hongo, Bunkyo-ku, Tokyo, Japan
Location of production:	Fukuda Denshi Co., Ltd. Shiroi Factory 305-1 Naka, Shiroi-shi, Chiba, Japan
Applied Annex:	Annex II of Directive 2014/53/EU
Technical file:	No. 063150D-24B09

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Takashi Nomura

General Manager

Quality Assurance Department

Appendix 1 (Details of the system components)

Device Name	Model	Type
DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200N
DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200NR
DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200NT
DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200NRT
DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200M
DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200MR
DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200MT
DYNASCOPE 1000 Series DS-1200 System	DS-1200	DS-1200MRT
CO_2 Gas Module	HC-110	HC-110
Gas Unit I/F Module	HC-120	HC-120
Multi Gas Module	MG-110	MG-110
Multi Gas Module S	MG-120	MG-120

Appendix 2 (List of Accessories)

Device Name	Type
Multi Module	HM-800
SpO2 Module	HG-810
SpO2 Module	HG-820
Multiport Module	HP-800