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-1700 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:	4538612021009S
Intended Purpose:	This device is a central monitor to monitor the conditions of the patients. It deals with the following vital sign parameters, which are measured and transmitted by the specified bedside monitors and /or the telemeters for use in combination. The vital signs are electrocardiogram, heart rate, respiration rate, body temperature, arterial oxygen saturation (SpO_2), pulse rate, invasive blood pressure, non-invasive blood pressure, CO_2 concentration, O_2 concentration and anesthetic gas concentration (including N_2O, 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. 063020H-20728

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-1700 System
Model:	DS-1700
Type:	DS-1708RE, DS-1708R, DS-1708E, DS-1708
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. 063020D-21503

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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-1700 System	DS-1700	DS-1708RE
DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1708R
DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1708E
DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1708
DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1700LRE
DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1700LR
DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1700LE
DYNASCOPE 1000 Series DS-1700 System	DS-1700	DS-1700L

Appendix 2 (List of Accessories)

Device Name	Type
Recorder Unit	HR-800