# 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.<br>2-35-8 Hongo, Bunkyo-ku, Tokyo 113-8420 Japan |
| Location of Design | Fukuda Denshi Co., Ltd.<br>2-35-27 Hongo, Bunkyo-ku, Tokyo 113-8420 Japan |
| Location of Production | Fukuda Denshi Co., Ltd. Shiroi Factory<br>305-1 Naka, Shiroi-shi, Chiba 270-1495 Japan |

| **Medical Device** | | |
|---|---|---|
| Product Category | Measuring and Monitoring Device for Vital Signs | |
| Device Name | DYNASCOPE 7000 series Central Monitor DS-7700 system<br>*Refer to the Appendix 1 for details. | ☒ MDR ((EU)2017/745)<br>☒ RoHS Directive (2011/65/EU)<br>☒ RE Directive (2014/53/EU) |
| | Reusable Accessories for DS-7700<br>*Refer to the Appendix 2 for details. | ☒ MDR ((EU)2017/745)<br>☒ RoHS Directive (2011/65/EU)<br>☐ 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<br>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 |

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Takashi Nomura
General Manager
Quality Assurance Department

**Appendix 1**

| **Medical Device description** | |
|---|---|
| Device Name | DYNASCOPE 7000 series Central Monitor DS-7700 system |
| GMDN / EMDN Code | GMDN<br>38470 (Patient monitoring system central station monitor)<br>EMDN<br>Z12030201 (CENTRAL INFORMATION COMPUTING SYSTEMS)<br>Z12030602 (VITAL SIGNS TELEMETRY RECEIVERS) |
| 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.<br>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 and anesthetic gas concentration (including N2O, halothane, isoflurane, enflurane, sevoflurane and desflurane). |
| Device Class | Class IIb |
| Device Classification Rule | Rule 10<br>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: 063020H-22215<br>RED: 063020D-17605, 063020D-17609 |
| Basic UDI-DI | 4538612021009S |

Details of the system components:

| No. | Device Name | Model | Type |
|---|---|---|---|
| 1 | DYNASCOPE 7000 series Central Monitor DS-7700 system | DS-7700 | DS-7780 |
| 2 | DYNASCOPE 7000 series Central Monitor DS-7700 system | DS-7700 | DS-7780W |
| 3 | DYNASCOPE 7000 series Central Monitor DS-7700 system | DS-7700 | DS-7700L |
| 4 | DYNASCOPE 7000 series Central Monitor DS-7700 system | DS-7700 | DS-7700WL |
| 5 | DYNASCOPE 7000 series Central Monitor DS-7700 system | DS-7700 | LW-7080 |

**Appendix 2**

| **Medical Device description** | |
|---|---|
| Device Name | Reusable Accessories for DS-7700 |
| EMDN Code | Z12030201 (CENTRAL INFORMATION COMPUTING SYSTEMS)<br>Z12030602 (VITAL SIGNS TELEMETRY RECEIVERS) |
| Intended Purpose | These are accessories to support DS-7700 or use to operate DS-7700.<br>DS-7700 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.<br>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 and anesthetic gas concentration (including N2O, halothane, isoflurane, enflurane, sevoflurane and desflurane). |
| Device Class | Class I (self-certified) |
| Device Classification Rule | Rule 1<br>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: 063020H-22215<br>RED: N/A |
| Basic UDI-DI | 4538612021019U |

Reusable Accessories for DS-7700 intended to be used in combination with DYNASCOPE 7000 series Central Monitor DS-7700 system.

| No. | Device Name | Model | Type |
|---|---|---|---|
| 1 | Recording Paper | OP-124TE 50/20M | - |
| 2 | CF Card | FCF-1000 | - |
| 3 | CF Card | FCF-128 | - |
| 4 | CF Card | FCF-16GA | - |
| 5 | Ethernet Branch Cable | CJ-522A | - |
| 6 | Ethernet Branch Cable | CJ-522B | - |
| 7 | Ethernet Branch Cable | CJ-522C | - |
| 8 | Ethernet Branch Cable | CJ-522D | - |
| 9 | Ethernet Branch Cable | CJ-522E | - |
| 10 | Connection Cable | CJ-530A | - |
| 11 | Connection Cable | CJ-530B | - |
| 12 | Connection Cable | CJ-530C | - |
| 13 | LAN Interface Cable (Cross) | CJ-761 | - |
| 14 | Whip Antenna | FUKU-435LF | - |
| 15 | RS-232C Cross cable | CJ-725 | - |
| 16 | Relay Cable (Straight) | CJ-726 | - |
| 17 | Power Cable | CS-18 | - |
| 18 | Power Cable | CS-55-ST | - |
| 19 | Power Cable | CS-55-RA | - |
| 20 | Power Cable | CS-56-ST | - |
| 21 | Power Cable | CS-57-ST | - |
| 22 | Power Cable | CS-57-RA | - |
| 23 | Power Cable | CS-58-ST | - |
| 24 | Power Cable | CS-59-ST | - |