By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 743406 R000

Manufacturer: Fukuda Denshi Co., Ltd.

Address:
3-39-4 Hongo,
Bunkyo-ku,
Tokyo
113-8483
Japan

Single Registration Number: JP-MF-000008253

EU Authorised Representative: Emergo Europe

Address:
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-08-30**

Current Issue Date: **2022-11-28**

Starting Validity Date: **2022-11-28**

Expiry Date: **2027-08-29**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Central Monitor	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 (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).
Bedside Monitor	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).

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ECG, Respiration and SpO2 Transmitter	This device intends to continuously transmit the vital signs to a specified monitor by wireless network. The measurable vital signs are electrocardiogram, respiration waveform, arterial oxygen saturation (SpO2) and pulse waveform.

Device Schedule: Class IIa devices

Device(s)	Risk Classification
Electrocardiograph	Class IIa
Sphygmomanometer and Sphygmograph	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-08-30	3373386	Issued.
Current	3805170	Supplemented - Addition of device categories; Central Monitor, Bedside Monitor, Electrocardiograph, and Sphygmomanometer and Sphygmograph. Amended - Removal of the subcontractor pages.

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