By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01342**

Issued To: **NIHON KOHDEN CORPORATION**
1-31-4 Nishiochiai
Shinjuku-Ku
Tokyo
161-8560
Japan

In respect of:

The design, development and manufacture of patient monitoring systems, CO2 monitors for medical application, pulse oximeters, defibrillators, internal defibrillator paddles, electrocardiographs, electroencephalographs, evoked potential measuring systems, ventilators and accessories.
Those aspects of Annex II related to securing and maintaining sterility in the design and manufacture of Laryngoscope Blade.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1996-07-01** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Supplementary Information to CE 01342

Issued To:

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Number	Device Name	Intended purpose per IFU
Class III		
MD 1103	Internal defibrillation paddle, ND-762V/763V/764V/ 765V/766V/767V	See CE 503071
MD 1103	Internal defibrillation paddle, ND-593V/594V/595V/ 596V/597V	See CE 503071
MD 1103	Internal defibrillation paddle, ND-863V/864V/865V/866V /867V, ND-893V/894V/895V/896V /897V	See CE 503071
Class IIb		
MD 1102	Ventilator	This device uses positive pressure to provide ventilation and ventilatory assistance as well as oxygen administration to adult or pediatric patients who have spontaneous breathing but need mechanical ventilation (patients with a tidal volume of 100 mL or more).
MD 1103	Automated external defibrillator	This device delivers short duration high-current electrical shock to patients to treat ventricular fibrillation and ventricular tachycardia.

First Issued: **1996-07-01** Date: **2021-04-29** Expiry Date: **2024-05-26**

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MD 1103	Defibrillators	This device delivers short-duration high-current electrical shock to patients to treat ventricular fibrillation and ventricular tachycardia. This device can measure ECG and perform asynchronous defibrillation as well as synchronized cardioversion to treat atrial flutter. In addition to manual defibrillation mode, it provides easy to use semiautomatic defibrillation in AED mode. Pacing function to treat temporary bradycardia is available depending on the model. Vital sign monitoring are available. (Available parameters depend on the model.)
MD1302	Electrocardiography telemetric monitoring system transmitter	This device derives and transmits vital signs data from a patient to a device such as a multi-purpose telemeter for continuous monitoring.
MD 1302	Evoked-potential graphic recording system	This device is intended to monitor, record, and display the bioelectric signals produced by sensory and motor pathways. The system measures and displays EP, EEG, EMG and skin temperature of distal portion of extremities to provide health care professionals with information to help assess a patient's neurological status.

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MD 1302	Neural Function Measuring System	This device is used as a nerve stimulator for surgical procedures and brain mapping during treatment of patients with seizure disorders and used for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency.
MD 1302	CO_2 Monitor	This device is intended to monitor respiratory rate, CO_2 partial pressure and $ETCO_2$. It is also intended to monitor pulse rate and SpO_2.
MD 1302	Pulse Oximeter	This device is installed near the patient to display the patient's vital signs (SpO_2, pulse rate, etc.) on the display and generate alarms.
MD 1302	Electrocardiography telemetric monitoring system receiver	This device can simultaneously monitor the multiple patients in different locations using radio telemetry. It can display the review data, such as trend graph, for each patient. This device can monitor each patient's vital signs data which are available on the transmitter or bedside monitor.
MD 1302	Multiple Patient Receiver	This device can receive the multiple patient's vital signs data from transmitters and send to a central monitor network. This device also processes the received vital sign information and judges alarms and sends the alarm information to the network.

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MD 1302	Bedside Monitor	This device is to be installed near the patient. The patient's vital signs can be monitored and alarms are generated.
MD 1302	Vital Sign Telemeter	This device is connected to a patient who requires monitoring and is mainly used as a telemetry system. It can be configured to display the patient's vital signs on the screen and generate alarms for use as a temporary simple monitor.
MD 1302	Multi gas unit	This device measures respiration gas concentration and respiration volume (depends on the model). This device is connected and used with bedside monitors.
MD 1302	Patient monitoring system central station monitor	This device is designed for use in various hospital environments, including the ICU, CCU, recovery room, and general ward. This device allows hospital staff to monitor several patients' vital signs.
MD 1302	Hemodynamic Unit	This device is installed near the patient for measurement of patient vital signs and other related information (arterial pressure, arterial blood temperature, injectate temperature and central venous oxygen saturation). This device can be used for continuous monitoring of circulatory variables such as cardiac output calculated using the pulse contour method, intrathoracic blood volume, volume of extravascular lung water, oxygen delivery rate, and oxygen consumption.

First Issued: **1996-07-01** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1302	Electrocardiograph	Not applicable for class IIa
MD 1302	Electroencephalograph	Not applicable for class IIa
MD 1302	SpO_2 sensor	Not applicable for class IIa
MD 1302	CO_2 sensor	Not applicable for class IIa
MD 1302	Patient monitoring system accessory (NMT Module)	Not applicable for class IIa
MD 1302	Evoked-potential measuring system accessory (Peripheral Nerve Stimulator)	Not applicable for class IIa
MD 0101	Ventilator accessories (Mask, Breathing circuit)	Not applicable for class IIa
Class Is		
MD 0106	Laryngoscope Blade	Not applicable for Class Is

First Issued: **1996-07-01** Date: **2021-04-29** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 01342**
Date:	**2021-04-29**
Issued To:	**NIHON KOHDEN CORPORATION** **1-31-4 Nishiochiai** **Shinjuku-Ku** **Tokyo** **161-8560** **Japan**

Subcontractor:	**Service(s) supplied**
GaleMed (Xiamen) Co., Ltd. Xiamen Area of China (Fujian) Pilot Free Trade Zone, 39, Section 3, Haijing East Road 361026 Fujian Province China	**Manufacture**
GaleMed Corporation No. 87, Li-Gong 2nd Road Wu-Jia I-Lan 268 Taiwan	**Manufacture**
Hsiner Co., Ltd. No. 312, Jhongshan Rd. Taichung City Shengang Dist. 429 Taiwan	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Jabil Circuit (Shanghai) Ltd. No. 600 Tian Lin Road Shanghai 200233 China	**Manufacture**
Nihon Kohden Corporation Kawamoto Factory 2909-63 Shirakusadai Fukaya-Shi Saitama 369-1106 Japan	**Manufacture**
Nihon Kohden Corporation Tokorozawa Office/Advanced Technology Center 1-1-6 Kusunokidai Tokorozawa-Shi Saitama 359-0037 Japan	**Design**

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Subcontractor:	**Service(s) supplied**
NIHON KOHDEN EUROPE GmbH Raiffeisenstrasse 10 D-61191 Rosbach Germany	**EU Representative** **Manufacture**
Nihon Kohden Tomioka Corporation 486 Nanokaichi Tomioka-Shi Gunma 370-2343 Japan	**Manufacture**
Nihon Kohden Tomioka Corporation Nihon Kohden Kawamoto Production Center 2909-63 Shirakusadai Fukaya-Shi Saitama 369-1106 Japan	**Manufacture**

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Subcontractor:	**Service(s) supplied**
NIHON KOHDEN TOMIOKA CORPORATION Tomioka Production Center 1-1 Tajino Tomioka-shi Gunma 370-2314 Japan	**Manufacture**
NIHON KOHDEN TOMIOKA CORPORATION Nihon Kohden Eastern Japan Logistics Center 2-1-1 Nishi Inter Sakado-shi Saitama 359-0259 Japan	**Manufacture**

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Subcontractor:	**Service(s) supplied**
NIHON KOHDEN TOMIOKA CORPORATION Tomioka Factory II 2027-1 Tomioka Tomioka-shi Gunma 370-2316 Japan	**Manufacture**
Nihon Vinyl Cord Corp. Kodama Second Factory 1401-1 Kodama, Kodama-machi Honjo-shi Saitama 367-0212 Japan	**Manufacture**
Nihon Vinyl Cord Corp. Shimoongata Factory 424-6 Shimoongata-machi Tokyo Hachioji-shi 192-0154 Japan	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Nihon Vinyl Cord Corp. Kodama Factory 1724-8 Kodama Kodama-machi Honjo-shi Saitama 367-0212 Japan	**Manufacture**
Otax Co., Ltd. 1215 Nippa-Cho Kohoku-ku, Yokohama-shi Kanagawa 223-8558 Japan	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Shanghai Kohden Medical Electronic Instrument Corporation No. 567 Huancheng Bei Road Shanghai Comprehensive Industrial Development Zone Fengxian District Shanghai 201401 China	**Manufacture**
Sumida Electric (Thailand) Co., Ltd. 148 Moo5, Bangkadi Industrial Park Tiwanon Road., Tambol Bangkadi Amphur Muang, Pathumthani 12000 Thailand	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Taiwan Advanced Sterilization Technology Inc. Taichung Export Processing Zone No.17-1, Chien Kuo Road Tan Tze Taichung City 427 Taiwan	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01342**
Date: **2021-04-29**
Issued To: **NIHON KOHDEN CORPORATION**
1-31-4 Nishiochiai
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Date	Reference Number	Action
01 July 1996		First issue.
26 January 1999		Changes to Sub-contractors list.
12 July 1999		Changes to Sub-contractors list.
17 January 2000		Changes to Sub-contractors list.
11 February 2000		Changes to Sub-contractors list.
03 March 2000		Changes to Sub-contractors list.
12 November 2001		Five years renewal.
21 February 2002		Changes to Sub-contractors list.
04 March 2002		Changes to Sub-contractors list.
11 November 2003		Changes to Sub-contractors list. New format certificate.
12 May 2004		Changes to Sub-contractors list.
03 February 2006		Re-issue certificate in new format. Change to address of Warehouse facility and administrative change to other Kawamoto factory address.
30 May 2006		Five year certificate renewal. Extension to scope to include 'internal defibrillator paddles'. Addition of Nihon Vinyl Cord Corp Tokyo and Kodama Factory as sub-contractors for manufacture.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01342**

Date: **2021-04-29**

Issued To: **NIHON KOHDEN CORPORATION**
1-31-4 Nishiochiai
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Date	Reference Number	Action
12 March 2007		Addition of Nihon Kohden Corporation Higashi-Nakano Office for Quality Assurance activities.
04 June 2010		Reissue due to addition of Jabil Circuit (Shanghai) Ltd for Manufacturing activities.
15 June 2011	7674704	Certificate renewal. Addition of "EU Representative" Nihon Kohden Europe GMBH Germany and addition of Analogic Corporation as subcontractor for manufacture.
17 January 2014	8106575	Reissue due to change of sub-contractor address for 'Nihon Vinyl Cord Corp' from '2-1141 Motohachioji-machi, Tokyo 193-0826' to '424-6 Shimoongata-machi, Tokyo 192-0154'.
13 April 2015	8318245	Reissue due to addition of 'Nihon Kohden Tomioka Corporation, Tomioka Production Center, 1-1 Tajino, Tomioka-shi, Gunma, 370-2314, Japan' as a significant subcontractor for manufacture.
03 July 2015	8361349	Reissue due to deletion of subcontractor, 'Analogic Corporation'.
19 June 2016	8521589	Certificate renewal. Change of Subcontractor Nihon Vinyl Cord Corp manufacturing facility from Kodama factory, 1724-8 to Kodama Second Factory, 1401-1.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01342**

Date: **2021-04-29**

Issued To: **NIHON KOHDEN CORPORATION**
1-31-4 Nishiochiai
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Date	Reference Number	Action
11 April 2017	8709399	Certificate Reissue. Change of scope statement to remove arrhythmia monitors and fetal monitors, and addition of intended use to CO2 monitors to be CO2 monitors for medical application. Deletion of Nihon Kohden Corporation Higashi Nakano Office. Addition of Nihon Kohden Corporation Tokorozawa Office/Advanced Technology Center. Addition of Nihon Kohden Tomioka Corporation Nihon Kohden Kawamoto Production Center. Change of address of Tsurugashima Office centre from Fujimi 6-Chome, Tsurugashima-shi, Saitama 350-2201 Japan to 6-2-20 Fujimi Tsurugashima-shi, Saitama 350-2201 Japan.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01342**
Date: **2021-04-29**
Issued To: **NIHON KOHDEN CORPORATION**
1-31-4 Nishiochiai
Shinjuku-Ku
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161-8560
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Date	Reference Number	Action
15 January 2019	8959615	Certificate reissue to add Ventilators and Accessories in the product scope, and addition of GaleMed (Xiamen) Co.,Ltd. and Hsiner Co., Ltd. in the significant subcontractor list as breathing circuit and mask subcontractors. Address change of Shanghai Kohden Medical Electronic Instrument Corp. Addition of comma after Nihon Vinyl Cord Corp. Remove of Tsurugashima Office Centre from significant subcontractor list. Address change of Otax Co.,Ltd.
13 March 2019	9717043	Certificate re-issue for additional scope "Those aspects of Annex II related to securing and maintaining sterility in the design and manufacture of Laryngoscope Blade." Addition of GaleMed Corporation and Taiwan Advanced Sterilization Technology Inc. to significant subcontractor list in association with above change.
15 March 2019	7780160	Traceable to NB 0086.

EC Certificate - Full Quality Assurance System Certificate History

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1-31-4 Nishiochiai
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Date	Reference Number	Action
Current	9774425	Certificate renewal. Deletion of cardiac catheterisation systems and ambulatory ECG analysis systems from the scope of the certificate. Addition of product table. Addition of significant subcontractors Nihon Kohden Tomioka Corporation Nihon Kohden Eastern Japan Logistics Center, Nihon Kohden Tomioka Corporation Tomioka Factory II, Nihon Vinyl Cord Corp. Kodama Factory and Sumida Electric (Thailand) Co., Ltd. Address change of Nihon KOHDEN EUROPE GmbH and GaleMed (Xiamen) Co.,Ltd.

NIHON KOHDEN CORPORATION
1-31-4 Nishiochiai
Shinjuku-ku
Tokyo
161-8560
Japan

2024-05-24

Notified Body Confirmation Letter

Reference: EU2023-607/ 829348

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

NIHON KOHDEN CORPORATION
1-31-4 Nishiochiai
Shinjuku-ku
Tokyo
161-8560
Japan

SRN Number (if available): JP-MF-000019022

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the

corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Internal defibrillation paddle ND-863V, ND-864V, ND-865V, ND-866V, ND-867V, ND-893V, ND-894V, ND-895V, ND-896V, ND-897V	Class III	Not Applicable	MDD Certificate #CE01342, NB #2797. MDD Certificate #CE503071, NB #2797
Internal defibrillation paddle ND-762V, ND-763V, ND-764V, ND-765V, ND-766V, ND-767V	Class III	Not Applicable	MDD Certificate #CE01342, NB #2797. MDD Certificate #CE503071, NB #2797
Internal defibrillation paddle ND-593V, ND-594V, ND-595V, ND-596V, ND-597V	Class III	Not Applicable	MDD Certificate #CE01342, NB #2797. MDD Certificate #CE503071, NB #2797
Automated External Defibrillator AED-3100	Class III	Not Applicable	MDD Certificate #CE01342, NB #2797
Defibrillator TEC-5611, TEC-5621, TEC-5631	Class III	Not Applicable	MDD Certificate #CE01342, NB #2797
Multi Parameter/SpO2 Unit QI-564V *TEC-5611, TEC-5621, TEC-5631 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Multi Parameter/SpO2/NIBP Unit QI-565V *TEC-5611, TEC-5621, TEC-5631 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
NIBP UNIT SG-565V *TEC-5611, TEC-5621, TEC-5631 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Defibrillator EMS-1052	Class III	Not Applicable	MDD Certificate #CE01342, NB #2797
Defibrillator TEC-8321K/8322K/8332K/8342K/8352K	Class III	Not Applicable	MDD Certificate #CE01342, NB #2797
12 Lead ECG Unit AC-831VA, AC-831VK *TEC-8321K/8322K/8332K/8342K/8352K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Automated External Defibrillator AED-2150K, AED-2151K, AED-2152K	Class III	Not Applicable	MDD Certificate #CE01342, NB #2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Pulse Oximeter ***OLV-4201***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Ventilator ***NKV-330***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Flow sensor ***TF-300Z*** *NKV-330 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Exhalation port ***VA-300Z*** *NKV-330 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Breathing circuit filter ***VA-301Z*** *NKV-330 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Humidification chamber ***VA-302Z*** *NKV-330 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Single limb breathing set HW-EXH ***VB-310Z*** *NKV-330 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Single limb breathing set WT-EXH ***VB-311Z*** *NKV-330 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Single limb breathing set EXH ***VB-312Z*** *NKV-330 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Single limb breathing set HW ***VB-313Z*** *NKV-330 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Bedside Monitor ***CSM-1501, CSM-1502, CSM-1701, CSM-1702***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
CORE UNIT ***CU-152R, CU-151R, CU-172R, CU-171R*** *CSM-1501, CSM-1502, CSM-1701, CSM-1702 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
MULTI AMP UNIT ***AA-174P*** *CSM-1501, CSM-1502, CSM-1701, CSM-1702 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Smart Expansion unit ***AA-672P, AA-674P*** *CSM-1501, CSM-1502, CSM-1701, CSM-1702 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Neuro Unit ***AE-918P*** *CSM-1501, CSM-1502, CSM-1701, CSM-1702 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Input unit ***AY-631P, AY-633P, AY-651P, AY-653P,*** ***AY-660P, AY-661P, AY-663P, AY-671P,*** ***AY-673P*** *CSM-1501, CSM-1502, CSM-1701, CSM-1702 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
DATA ACQUISITION UNIT ***JA-170P*** *CSM-1501, CSM-1502, CSM-1701, CSM-1702 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
REAR OPTION BOARD ***QI-151P, QI-171P*** *CSM-1501, CSM-1502, CSM-1701, CSM-1702 Accessory*	Class IIb - Implantable - Non WET	Not Applicable	MDD Certificate #CE01342, NB #2797
SIDE OPTION BOARD ***QI-152P*** *CSM-1501, CSM-1502, CSM-1701, CSM-1702 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Memory unit ***QM-600P*** *CSM-1501, CSM-1502, CSM-1701, CSM-1702 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Alarm Indicator ***YL-920P*** *CSM-1501, CSM-1502, CSM-1701, CSM-1702 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Bedside Monitor, ***PVM-4731, PVM-4733, PVM-4751, PVM-4753, PVM-4761, PVM-4763***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Interface ***QI-470P*** *PVM-4731, PVM-4733, PVM-4751, PVM-4753, PVM-4761, PVM-4763 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Wireless LAN station ***QI-520P*** *PVM-4731, PVM-4733, PVM-4751, PVM-4753, PVM-4761, PVM-4763 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Recorder module ***WS-470P*** *PVM-4731, PVM-4733, PVM-4751, PVM-4753, PVM-4761, PVM-4763 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Transmitter ***ZS-600P*** *PVM-4731, PVM-4733, PVM-4751, PVM-4753, PVM-4761, PVM-4763 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Bedside Monitor ***BSM-1733, BSM-1753, BSM-1763, BSM-1773***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Wireless LAN Station ***QI-170P*** *BSM-1733, BSM-1753, BSM-1763, BSM-1773 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Vital Sign Telemeter ***GZ-130P***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Vital Sign Telemeter ***GZ-140P***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Bedside Monitor ***BSM-6301K, BSM-6501K, BSM-6701K***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Main unit ***MU-671RK, MU-651RK, MU-631RK*** *BSM-6301K, BSM-6501K, BSM-6701K Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Interface ***QI-671P, QI-672P, QI-631P, QI-632P, QI-634P*** *BSM-6301K, BSM-6501K, BSM-6701K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Data Aquisition unit ***JA-690PA, JA-694PA*** *BSM-6301K, BSM-6501K, BSM-6701K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Interface unit ***QI-600P*** *BSM-6301K, BSM-6501K, BSM-6701K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Recorder Module ***WS-671P*** *BSM-6301K, BSM-6501K, BSM-6701K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Bedside Monitor, ***PVM-2701/2703***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Interface ***QI-201P, QI-202P*** *PVM-2701/2703 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Bedside Monitor ***BSM-3532, BSM-3552, BSM-3562, BSM-3733, BSM-3753, BSM-3763***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Recorder Module ***WS-371P*** *BSM-3532, BSM-3552, BSM-3562, BSM-3733, BSM-3753, BSM-3763 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Interface ***QI-371P, QI-372P*** *BSM-3532, BSM-3552, BSM-3562, BSM-3733, BSM-3753, BSM-3763 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Smart Expansion unit ***AA-372P, AA-374P*** *BSM-3532, BSM-3552, BSM-3562, BSM-3733, BSM-3753, BSM-3763 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Bedside Monitor, ***CSM-1901***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Core Unit ***CU-191RK, CU-192RK*** *CSM-1901 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Recorder Unit ***WS-960P*** *CSM-1901 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Multi Amp Unit ***AA-910P*** *CSM-1901 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Central Monitor, ***CNS-6201***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Central Monitor Processing Unit ***PU-621R*** *CNS-6201 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Alarm Indicator ***YL-611P, YL-612P*** *CNS-6201 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Multiple Patient Receiver, ***ORG-9100K***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Telemetry System ***WEP-5204K, WEP-5208K***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Interface ***QI-521P*** *WEP-5204K, WEP-5208K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Memory card ***QM-601P*** *WEP-5204K, WEP-5208K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Transmitter ***ZM-530P***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Transmitter ***ZS-620P***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Transmitter ***ZM-540P***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Transmitter ***ZS-630P***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
EMG/EP Measuring System ***MEB-9600***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
MAIN UNIT ***DC-960B*** *MEB-9600 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
ELECTRODE JUNCTION BOX ***JB-962B, JB-964B*** *MEB-9600 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
CONTROL UNIT ***GG-961BK, GG-962BK*** *MEB-9600 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
REVIEW SOFTWARE ***QP-219BK*** *MEB-9600 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
EMG/EP Measuring System ***MEB-2300K***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
ACTIVE ELECTRODE CABLE ***BM-230B*** *MEB-2300K Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
PC UNIT ***CC-230BK*** *MEB-2300K Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
MAIN UNIT ***DC-230BK*** *MEB-2300K Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
ELECTRODE JUNCTION BOX ***JB-206B, 212B*** *MEB-2300K Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
CART ***KD-030AK*** *MEB-2300K Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
CONSTANT CURRENT STIMULATION UNIT ***MS-230B*** *MEB-2300K Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
CONTROL PANEL UNIT ***PV-230B*** *MEB-2300K Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
TREND MONITORING SOFTWARE ***QP-258BK*** *MEB-2300K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
AUTONOMIC NERVE MEASUREMENT SOFTWARE QP-259BK *MEB-2300K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
EVENT RELATED POTENTIAL SOFTWARE ***QP-260BK*** *MEB-2300K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Neural function measuring system ***MEE-2000***	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
PC UNIT ***CC-201BK, CC-202BK*** *MEE-2000 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
MAIN UNIT ***DC-200B*** *MEE-2000 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
AMP UNIT ***JB-232B, JB-316B, JB-916B*** *MEE-2000 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
STIMULATION POD ***JS-201B, JS-202B, JS-203B, JS-204B, JS-209B*** *MEE-2000 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
TcMEP SWITCH BOX ***JS-210B*** *MEE-2000 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
LED FLASH ***LS-103B*** *MEE-2000 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
EEG NEEDLE ELECTRODE ***NE-224S*** *MEE-2000 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
ADVANCED AUDITORY EVOKED POTENTIALS PROGRAM ***QP-101BK*** *MEE-2000 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ESU DETECTION PROBE YB-201B *MEE-2000 Accessory*	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
HEMODYNAMIC UNIT AP-170P	Class IIb - Non Implantable	Not Applicable	MDD Certificate #CE01342, NB #2797
Electroencephalograph EEG-1200K	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
PC unit CC-120AK *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Electrode junction box JE-120A, JE-921A, JE-921AG *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Photic Stimulator Control Unit LS-120AK *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Flash Lamp Assembly LS-703A, LS-706A *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Extension unit MS-120BK *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Switch box PE-210AK *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Amp unit QA-120A *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Input box converter QI-123A *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Interface unit QI-124A *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Digital video software QP-110AK *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Review program QP-112AK *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
EEG Trend program QP-160AK *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
EEG mapping program QP-220AK *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Spike detector software ***QP-251AK*** *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Multyiple Portable Socket Outlet ***SD-903AK, SD-120AK*** *EEG-1200K Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Electroencephalogragh ***EEG-1250***	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
PC Unit ***CC-125A*** *EEG-1250 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Neuro Unit ***AE-920P***	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
EEG Head Set ***AE-120A***	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
WIRELESS INPUT UNIT ***WEE-1200***	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Telemetry unit ***ZB-120A*** *WEE-1200 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
MAIN UNIT ***MU-120A*** *WEE-1200 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
CO2 Sensor Kit ***TG-980P, TG-981T, TG-981T1, TG-981T4***	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
CO2 Sensor Kit ***TG-920P, TG-921T, TG-921T3***	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
CO2 Sensor ***TG-121T, TG-121TW*** *TG-920P, TG-921T, TG-921T3 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
CO2 Adapter ***JG-920P, JG-921T, JG-921T3*** *TG-920P, TG-921T, TG-921T3 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
CO2 Sensor Kit ***TG-900P, TG-901T, TG-901T3***	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
CO2 Sensor ***TG-101T, TG-101TW,*** *TG-900P, TG-901T, TG-901T3 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
CO2 Adapter ***JG-900P, JG-901T, JG-901T3*** *TG-900P, TG-901T, TG-901T3 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
CO2 Sensor Kit ***TG-901T4***	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
CO2 Adaptor JG-901T4 *TG-901T4 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
CO2 Sensor Kit TG-921T4	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
CO2 Adaptor JG-921T4 *TG-921T4 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Multigas Unit GF-310R, Multigas/Flow unit GF-320R	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Multigas Unit GF-210R, Multigas/Flow unit GF-220R	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
SpO2 adapter JL-500P1, JL-500P2, JL-550T1, JL-550T2, JL-551T1, JL-551T2	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
SpO2 Adapter JL-570T	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
SpO2 Adapter JL-639P	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
NPPV full face mask set L/M/S/XS VM-310Z, VM-311Z, VM-312Z, VM-313Z, Child/infant NPPV full face mask XL/L VM-321Z, VM-322Z	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
NPPV cap-ONE mask set VM-330Z, VM-331Z, VM-332Z, VM-333Z	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
SpO2 Probe TL-271T, TL-272T, TL-273T, TL-274T, TL-271T3, TL-272T3, TL-273T3, TL-274T3	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Finger Probe TL-630T1, TL-630T3	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Disposable SpO2 Probe TL-535U	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
SpO2 PROBE TL-273TA	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Finger Probe TL-201T	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Multi-site Y Probe TL-260T	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Multi-site Probe ***TL-220T***	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Finger Probe ***TL-601T0, TL-631T1, TL-631T3***	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
NMT MODULE ***AF-101P***	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Electrocardiograph ***ECG-2450***	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Input Box ***JD-211D, JD-211DA, JD-212D, JD-213D*** *ECG-2450 Accessory*	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
Electrocardiograph ***ECG-3350***	Class IIa	Not Applicable	MDD Certificate #CE01342, NB #2797
NK PBLADE, ***ITL-SL/ITL-PL/ITL-NL/ITL-TL***	Class Is	Not Applicable	MDD Certificate #CE01342, NB #2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable			

Confirmation Letter Revision History

Date	Action
2024-04-15	Initial issue
2024-05-24	New devices and accessories applied for MDR in addition to the following products Pulse Oximeter OLV-4201 Ventilator NKV-330 Bedside Monitor CSM-1501, CSM-1502 CSM-1701, CSM-1702 Transmitter ZM-530P HEMODYNAMIC UNIT AP-170P CO2 Censor Kit TG-980P NPPV Full Face mask set VM-310Z, VM-311Z, VM-312Z, VM-313Z, VM-321Z, VM-322Z Automated External Defibrillator AED-3100 Defibrillator TEC-5611, TEC-5621, TEC-5631 Defibrillator EMS-1052 Internal defibrillation paddle, ND-863V/864V/865V/866V/867V ND-893V/894V/895V/896V/897V NK PBLADE ITL-SL, ITL-PL, ITL-NL, ITL-TL