

# 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

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Number	Device Name	Intended purpose per IFU
<b>Class III</b>		
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
<b>Class IIb</b>		
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.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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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 <sub>2</sub> Monitor	This device is intended to monitor respiratory rate, CO <sub>2</sub> partial pressure and ETCO <sub>2</sub> . It is also intended to monitor pulse rate and SpO <sub>2</sub> .
MD 1302	Pulse Oximeter	This device is installed near the patient to display the patient's vital signs (SpO <sub>2</sub> , 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.

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Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD 1302	Electrocardiograph	Not applicable for class IIa
MD 1302	Electroencephalograph	Not applicable for class IIa
MD 1302	SpO <sub>2</sub> sensor	Not applicable for class IIa
MD 1302	CO <sub>2</sub> 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
<b>Class Is</b>		
MD 0106	Laryngoscope Blade	Not applicable for Class Is

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# 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:

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

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

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

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

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

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**Japan**

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

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

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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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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.

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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.

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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.

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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.



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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.