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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, arrhythmia monitors, fetal monitors, CO2 monitors, pulse oximeters, cardiac catheterisation systems, defibrillators, internal defibrillator paddles, electrocardiographs, ambulatory ECG analysis systems, electroencephalographs and evoked potential measuring systems

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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **01 July 1996** Date: **19 June 2016** Expiry Date: **30 June 2021**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated by regular audit and surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the manufacturer named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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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:

Certificate No: **CE 01342**

Date: **19 June 2016**

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

Subcontractor:	Service(s) supplied
Jabil Circuit (Shanghai) Ltd 600 Tian Lin Road Shanghai 200233 China	**Manufacture**
Nihon Kohden Corporation Higashi-Nakano Office 3-14-20, Higashi-Nakano Nakano-ku Tokyo 164-0003 Japan	**Quality Assurance**
Nihon Kohden Corporation Kawamoto Factory 2909-63 Shirakusadai Fukaya-Shi Saitama 369-1106 Japan	**Manufacture**

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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:

Certificate No: **CE 01342**

Date: **19 June 2016**

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

Subcontractor:	Service(s) supplied
Nihon Kohden Corporation Tsurugashima Office Centre Fujimi 6-Chome Tsurugashima-Shi Saitama 350-2201 Japan	**Warehousing**
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**

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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:

Certificate No: **CE 01342**

Date: **19 June 2016**

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

Subcontractor:	Service(s) supplied
NIHON KOHDEN TOMIOKA CORPORATION Tomioka Production Center 1-1 Tajino Tomioka-shi Gunma 370-2314 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 Hachioji-shi Tokyo 192-0154 Japan	**Manufacture**

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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:

Certificate No: **CE 01342**

Date: **19 June 2016**

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

Subcontractor:	Service(s) supplied
Otax Co., Ltd. 1215 Nippa-Cho Kohoku-Ku, Yokohama Kanagawa 223-0057 Japan	**Manufacture**
Shanghai Kohden Medical Electronic Instrument Corporation 567 Huancheng Bei Road Shanghai Comprehensive Industrial Development Zone Shanghai China	**Manufacture**

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EC Certificate - Full Quality Assurance System
Certificate History

Certificate No: **CE 01342**
Date: **19 June 2016**
Issued To: **NIHON KOHDEN CORPORATION**
1-31-4 Nishiochiai
Shinjuku-Ku
Tokyo
161-8560
Japan

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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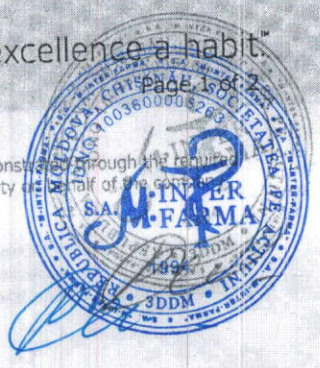

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01342**

Date: **19 June 2016**

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

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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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex V
(Devices in class I with measuring function)

No. G2M 063105 0048 Rev. 00

Manufacturer:	**CA-MI S.R.L.** Via Ugo La Malfa, 13 Frazione Pilastro 43013 Langhirano (PR) ITALY
Facility(ies):	CA-MI S.R.L. Via Ugo La Malfa, 13, Frazione Pilastro, 43013 Langhirano (PR), ITALY
Product Category(ies):	**Various canister, suction unit, aneroid sphygmomanometer and mercury free clinical thermometer**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:	ITA1319360M
Valid from:	2019-09-26
Valid until:	2024-05-26

Date, 2019-09-26

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 063105 0047 Rev. 00

Manufacturer:

CA-MI S.R.L.
Via Ugo La Malfa, 13
Frazione Pilastro
43013 Langhirano (PR)
ITALY

Facility(ies):

CA-MI S.R.L.
Via Ugo La Malfa, 13, Frazione Pilastro, 43013 Langhirano (PR),
ITALY

Product Category(ies):

Aerosol Therapy Equipment, Kits for Aerosol Therapy, Thermal Water Inhaler, Suction Unit, Surgical Suction Equipment, Breast Pump, Kit Accessory for Electric Breast Pump, Blood Pressure Monitor, Electronic Thermometer, Infrared Ear Thermometer, Tens Device, Pulse Oximeter

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: JTA1319360

Valid from: 2019-10-01
Valid until: 2024-05-26

Date, 2019-10-01

Stefan Preiß
Head of Certification/Notified Body

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D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 063105 0045 Rev. 01

Holder of Certificate: **CA-MI S.R.L.**
Via Ugo La Malfa, 13
Frazione Pilastro
43013 Langhirano (PR)
ITALY

Certification Mark:

TÜV SÜD
tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production, sale and after-sales technical assistance of medical equipments for surgery (electrical and manual suction pumps), electric breast pumps, medical devices for breathing (aerosol therapy equipments and thermal water inhaler), medical devices for stimulation (tens) and related accessories. Placing on the market under its own name of devices for monitoring of vital physiological parameters (pulse oximeters, thermometers, blood pressure monitors, sphygmomanometer and stethoscopes), incentive spirometers, devices for phlebology (graduated compression medical stockings) and anti-decubitus mattress.**
Distribution of active and non-active non implantable medical devices.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: ITA1254731

Valid from: 2019-08-01
Valid until: 2022-07-31

Date, 2019-07-30

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV SÜD ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 : 07.17

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 063105 0045 Rev. 01

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): CA-MI S.R.L.
Via Ugo La Malfa, 13, Frazione Pilastro, 43013 Langhirano (PR), ITALY

CA-MI S.r.l.
Via Strada per Parma 34, Frazione Pilastro, 43013 Langhirano PR, ITALY

Facility(ies) Scope:

CA-MI S.R.L.
Via Ugo La Malfa, 13, Frazione Pilastro, 43013 Langhirano (PR), ITALIA
Design and development, production, sale and after-sales technical assistance of medical equipments for surgery (electrical and manual suction pumps), electric breast pumps, medical devices for breathing (aerosol therapy equipments and thermal water inhaler), medical devices for stimulation (tens) and related accessories. Placing on the market under its own name of devices for monitoring of vital physiological parameters (pulse oximeters, thermometers, blood pressure monitors, sphygmomanometer and stethoscopes), incentive spirometers, devices for phlebology (graduated compression medical stockings) and anti-decubitus mattress.
Distribution of active and non-active non implantable medical devices.

CA-MI S.R.L.
Via Strada per Parma, 34, Frazione Pilastro, 43013 Langhirano (PR) Italy
Warehouse of active and non-active non implantable medical devices and components used in production

TÜV SÜD ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17