

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**

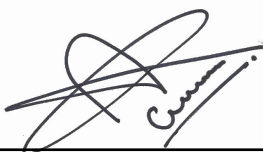
In respect of:

The design, development and manufacture of patient monitoring systems, CO2 monitors for medical application, pulse oximeters, cardiac catheterisation systems, defibrillators, internal defibrillator paddles, electrocardiographs, ambulatory ECG analysis systems, 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):



Albert Roossien, Regulatory Lead

First Issued: **1996-07-01**

Date: **2019-03-15**

Expiry Date: **2021-06-30**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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: **2019-03-15**
 Issued To: **NIHON KOHDEN CORPORATION**
1-31-4 Nishiochiai
Shinjuku-Ku
Tokyo
161-8560
Japan

| Subcontractor: | Service(s) supplied |
|--|---------------------|
| GaleMed (Xiamen) Co.,Ltd. Amoy Export Processing Zone 39 Section3, Haijing East Road Fujian Province 361026 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 v.d.H. 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
Tomiooka Production Center
1-1 Tajino
Tomiooka-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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Japan

| Subcontractor: | Service(s) supplied |
|---|---------------------|
| Otax Co., Ltd. 1215 Nippa-Cho Kohoku-ku, Yokohama-shi Kanagawa 223-8558 Japan | Manufacture |
| Shanghai Kohden Medical Electronic Instrument Corporation No. 567 Huancheng Bei Road Shanghai Comprehensive Industrial Development Zone Fengxian District Shanghai 201401 China | Manufacture |

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Japan

Subcontractor:

Service(s) supplied

Taiwan Advanced Sterilization Technology Inc.
 Taichung Export Processing Zone
 No. 17-1, Chien Kuo Rd.
 Tan Tze
 Taichung City
 427
 Taiwan

ETO Sterilization

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EC Certificate - Full Quality Assurance System

Certificate History

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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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This certificate was issued electronically and is bound by the conditions of the contract.

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.

A member of BSI Group of Companies.

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|-----------------|------------------|---|
| 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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|---------------|------------------|---|
| 11 April 2017 | 8709399 | <p>Certificate Reissue.</p> <p>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.</p> <p>Deletion of Nihon Kohden Corporation Higashi Nakano Office.</p> <p>Addition of Nihon Kohden Corporation Tokorozawa Office/Advanced Technology Center.</p> <p>Addition of Nihon Kohden Tomioka Corporation Nihon Kohden Kawamoto Production Center.</p> <p>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.</p> |

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| 15 January 2019 | 8959615 | <p>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.</p> <p>Address change of Shanghai Kohden Medical Electronic Instrument Corp.</p> <p>Addition of comma after Nihon Vinyl Cord Corp.</p> <p>Remove of Tsurugashima Office Centre from significant subcontractor list.</p> <p>Address change of Otax Co.,Ltd.</p> |
| 13 March 2019 | 9717043 | <p>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.</p> |
| Current | 7780160 | Traceable to NB 0086. |

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