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):

Digitally signed by Matei Vasile
Date: 2021.05.31 14:05:25 EEST
Reason: MoldSign Signature
Location: Moldova

Frank Lee, EMEA Compliance & Risk Director

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

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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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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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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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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**

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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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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