

認

証

嘱託人日本光電工業株式会社品質管理統括部薬事・法規管理部法規管理二課課長犬塚彰の代理人山本博史は、本公証人に対し、前記犬塚彰が添付書面の署名につき、自らしたものであることを承認している旨陳述した。

よって、これを認証する。

平成28年 10 月 14 日、本公証人役場において

東京都練馬区豊玉北5-17-12 練馬駅前ビル3階

東京法務局所属

公証人

Notary

長野哲生

Tetsuo NAGANO

証

明



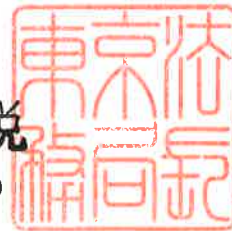
上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、真実のものであることを証明する。

平成28年 10 月 14 日

東京法務局長

佐藤主税

Chikara SATO



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN

This public document

2. has been signed by Tetsuo NAGANO

3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau

4. bears the seal/stamp of Tetsuo NAGANO, Notary

Certified

5. at Tokyo

6. 14 October 2016

7. by the Ministry of Foreign Affairs

8. 16-**N0 045619**

9. Seal/stamp:

10. Signature



A. Ogawa

Ayako OGAWA

For the Minister for Foreign Affairs



(Translation)

Registered No. 126, 2016

Certificate of Acknowledgment of Notary

On this 14th day of October, 2016, before me, Tetsuo NAGANO, a notary in and for Tokyo Legal Affairs Bureau, personally appeared Hiroshi YAMAMOTO, with satisfactory evidence of his identification and of his being the agent of Akira INUZUKA, Manager of Quality Management Division of NIHON KOHDEN CORPORATION, in accordance with the Notary Law of Japan stated that the principal, said Akira INUZUKA, had acknowledged to have affixed his signature to the attached document.

Witness, I set my hand and seal

Tetsuo NAGANO
Notary, Nerima Notary's Office
Tokyo Legal Affairs Bureau
5-17-12 Toyotamakita, Nerima-ku, Tokyo

To whom it may concern,

October 14, 2016

Certificate of Documentation

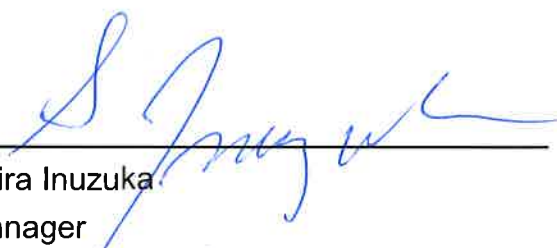
Dear Sir,

NIHON KOHDEN CORPORATION (1-31-4 Nishiochiai, Shinjuku-ku, Tokyo 161-8560, Japan), hereby certifies that the copy attached is taken from genuine original document.

Document;

1. EC Certificate Full Quality Assurance System (CE01342)

NIHON KOHDEN CORPORATION



Akira Inuzuka

Manager

Quality Management Division

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 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: **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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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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 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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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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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 Certificate History

Certificate No: CE 01342
Date: 19 June 2016
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 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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