

EU/RE DIRECTIVE DECLARATION OF CONFORMITY
適合宣言書

This is a declaration made in accordance with the requirements of Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment. The declaration of conformity is issued under the sole responsibility of the manufacturer.



Manufacturer's Name: NIHON KOHDEN CORPORATION
Business Address: 1-31-4 Nishiochiai, Shinjuku-ku
Tokyo 161-8560, Japan

European Representative: NIHON KOHDEN EUROPE GmbH
Address: Raiffeisenstrasse 10, D - 61191 Rosbach, Germany

Product Name and Model Name: (BEDSIDE MONITOR) CORE UNIT CU-152R
(BEDSIDE MONITOR) CORE UNIT CU-151R
(BEDSIDE MONITOR) CORE UNIT CU-172R
(BEDSIDE MONITOR) CORE UNIT CU-171R

Notified Body's Name and No.: Telefication B.V., Inc., No.0560(Module B)

EU-Type examination Certificate No.: 182140433/AA/00

Standard Applied: EN 62311: 2008
IEC 60601-1: 2005
IEC 60601-1 Amendment 1: 2012
IEC 60601-1-2: 2007
EN 300 328 V2.1.1
EN 301 893 V2.1.1
EN 302 567 V1.2.1
EN 302 567 V2.0.22
(only clause 4.2.7 Receiver Adjacent Channel Rejection is applied.)

Authorized Signatory:

Tokyo, Japan / 04 December 2018

Place and date of issue



Yoshiyuki Fujita
General Manager
Quality Management Division

EC/MDD DECLARATION OF CONFORMITY

適合宣言書

This is a declaration made in accordance with the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).



Manufacturer's Name: NIHON KOHDEN CORPORATION
Business Address: 1-31-4 Nishiochiai, Shinjuku-ku
Tokyo 161-8560, Japan

European Representative: NIHON KOHDEN EUROPE GmbH
Address: Raiffeisenstrasse 10, D - 61191 Rosbach, Germany

| | | |
|-------------------------------------|--------------------------------------|----------|
| Product Name and Model Name: | BEDSIDE MONITOR | CSM-1501 |
| | BEDSIDE MONITOR | CSM-1502 |
| | (BEDSIDE MONITOR) CORE UNIT | CU-152R |
| | (BEDSIDE MONITOR) CORE UNIT | CU-151R |
| | MULTI AMP UNIT | AA-174P |
| | SOFTWARE KIT | QS-116P |
| | SYNTHESIZED 18 LEAD FUNCTION LICENCE | QL-004P |
| | esCCO LICENCE | QL-005P |
| | esCCO/ HEMODYNAMICS GRAPH LICENCE | QL-006P |
| | BEDSIDE MONITOR | CSM-1701 |
| | BEDSIDE MONITOR | CSM-1702 |
| | (BEDSIDE MONITOR) CORE UNIT | CU-172R |
| | (BEDSIDE MONITOR) CORE UNIT | CU-171R |
| | SOFTWARE KIT | QS-127P |

Classification: IIb

Each kind of medical device to which the Full Quality Assurance Procedures (Annex II) have been applied complies with the applicable provisions of the essential requirements, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

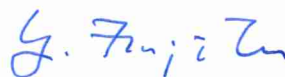
Notified Body: British Standard Institution
EC Certificate: CE 01342

Standard Applied: EN ISO 13485: 2016
EN ISO 14971: 2012
EN ISO 15223-1: 2016
IEC 60601-1: 2005
IEC 60601-1 Amendment 1: 2012
IEC 60601-1-2: 2007
IEC 60601-1-6: 2010
IEC 60601-1-6 Amendment 1: 2013
IEC 60601-1-8: 2006
IEC 60601-1-8 Amendment 1: 2012
IEC 60601-2-26: 2012
IEC 60601-2-27: 2011
IEC 80601-2-30: 2009

IEC 80601-2-30 Amendment 1: 2013
IEC 60601-2-34: 2011
IEC 60601-2-49: 2011
ISO 80601-2-55: 2011
ISO 80601-2-56: 2009
ISO 80601-2-61: 2011
IEC 62304: 2015
IEC 62366: 2007
IEC 62366 Amendment 1: 2014
EN 1041: 2008
EN 1041 Amendment 1: 2013

Authorized Signatory:Tokyo, Japan / 04 December 2018

Place and date of issue



Yoshiyuki Fujita
General Manager
Quality Management Division

RoHS DECLARATION OF CONFORMITY

RoHS 指令適合宣言書

This is a declaration made in accordance with the requirements of Council Directive 2011/65/EU of 8 June 2011 concerning the restriction of the use of certain hazardous substances in electrical and electronic equipment.



Manufacturer's Name/製造業者: NIHON KOHDEN CORPORATION/日本光電工業株式会社
Business Address/所在地: 1-31-4 Nishiochiai, Shinjuku-ku, Tokyo 161-8560, Japan
東京都新宿区西落合 1-31-4

We hereby certify that following product(s) conform to the European Union's Restriction on Use of Hazardous Substances in Electrical and Electronic equipment (RoHS) Directive 2011/65/EU for six regulated substances listed below.

下記の対象製品が、電気電子機器における下記6種類の有害物質の使用を制限する RoHS 指令に適合することを証明致します。

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| Product Name(s) /対象製品: | BEDSIDE MONITOR | CSM-1501 |
| | BEDSIDE MONITOR | CSM-1502 |
| | (BEDSIDE MONITOR) CORE UNIT | CU-152R |
| | (BEDSIDE MONITOR) CORE UNIT | CU-151R |
| | MULTI AMP UNIT | AA-174P |
| | RECORDER UNIT | WS-151P |
| | REAR OPTION BOARD | QI-151P |
| | SIDE OPTION BOARD | QI-152P |
| | SIDE OPTION BOARD | QI-153P |
| | SD CARD | QM-150P |
| | SSD EXTENTION KIT | YS-116P0 |
| | DVI-D-DVI-D CABLE2.5M | YS-116P1 |
| | DVI-D-DVI-D CABLE5M | YS-116P2 |
| | DVI-D-HDMI CABLE5M | YS-116P3 |
| | DVI-I-RGB CABLE2M | YS-116P4 |
| | DVI-I-RGB CABLE5M | YS-115P5 |
| | DVI-I-DVI-I CABLE10M | YS-116P6 |
| | HDMI CABLE10M | YS-116P7 |
| | HDMI CABLE5M | YS-116P8 |
| | UNIT HOLDER | DH-150P |
| | HOLDER | DH-155P |
| | UNIT HOLDER | DH-156P |
| | ADAPTER | DH-157P |
| | MOUNT ADAPTER | DH-320P |
| | HANDLE | DZ-150P |
| | INTERFACE MOUNT | DH-916P |
| | BEDSIDE MONITOR | CSM-1701 |
| | BEDSIDE MONITOR | CSM-1702 |
| | (BEDSIDE MONITOR) CORE UNIT | CU-172R |
| | (BEDSIDE MONITOR) CORE UNIT | CU-171R |
| | RECORDER MODULE | WS-171P |
| | REAR OPTION BOARD | QI-171P |
| | DATA ACQUISITION UNIT | JA-170P |

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| SD CARD | QM-151P |
| DAU CONNECTION CABLE 0.9M | YS-118P0 |
| DAU CONNECTION CABLE 2.8M | YS-118P1 |
| DAU CONNECTION CABLE 5M | YS-118P2 |
| DAU CONNECTION CABLE 10M | YS-118P3 |
| RECORDER CABLE 1.5M | YS-118P8 |
| RECORDER CABLE 0.35M | YS-118P9 |
| HDMI CABLE 10M | YS-119P1 |
| HDMI CABLE 30M | YS-119P2 |
| HDMI CABLE 50M | YS-119P3 |
| ADAPTER | DH-151P |
| CHANNEL ADAPTER | DH-152P |
| RECORDER HOLDER | DH-153P |
| IF HOLDER | DH-154P |
| GF HOLDER | DH-158P |
| UNIT HOLDER | DH-159P |
| CART | KC-150P |
| STAND | DM-150P |
| WALL MOUNT | KG-150P |
| UNIT HOLDER | DH-190P |
| WIRELESS COMMUNICATION MODULE | QI-150P |

List of environmentally hazardous substances/対象環境負荷物質:

- 1) Lead /鉛
- 2) Mercury/水銀
- 3) Cadmium/カドミウム
- 4) Hexavalent Chromium/六価クロム
- 5) Polybrominated biphenyls (PBB) /ポリ臭化ビフェニール
- 6) Polybrominated diphenyl ethers (PBDE) /ポリ臭化ジフェニルエーテル

Harmonised Standards Applied/適用整合規格: EN 50581:2012**Authorised Signatory:**

Tokyo, Japan/ 04 December 2018

Place and date of issue
発行日及び発行場所Yoshiyuki Fujita
General Manager
Quality Management Division
日本光電工業株式会社
品質管理統括部 部長 藤田 吉之