

EC/MDD DECLARATION OF CONFORMITY

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	BSM-3532
Bedside Monitor	BSM-3552
Bedside Monitor	BSM-3562
Bedside Monitor	BSM-3572
Bedside Monitor	BSM-3733
Bedside Monitor	BSM-3753
Bedside Monitor	BSM-3763
Bedside Monitor	BSM-3773
Software Kit	QS-058PK
Software Kit	QS-062P
Smart Expansion unit	AA-372P
Smart Expansion unit	AA-374P

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: BSI Group The Netherlands B.V.
EC Certificate: CE 01342

Standard Applied:

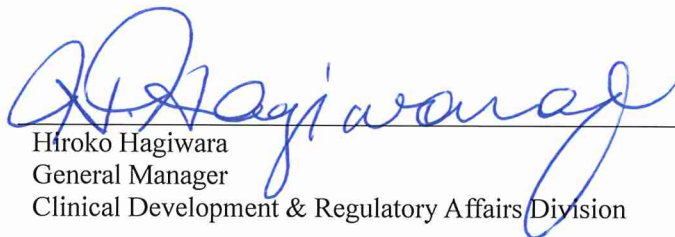
- EN ISO 13485: 2016
- EN ISO 14971: 2012
- EN ISO 15223-1: 2016
- IEC 60601-1: 2005
- IEC 60601-1 Amendment 1: 2012
- IEC 60601-1-2: 2007
- IEC 60601-1-6: 2010
- IEC 60601-1-6 Amendment 1: 2013
- IEC 60601-1-8: 2006
- IEC 60601-1-8 Amendment 1: 2012
- IEC 60601-2-26: 2012
- IEC 60601-2-27: 2011
- IEC 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: 2006
IEC 62366: 2007
IEC 62366 Amendment 1: 2014
EN 1041: 2008
EN 1041 Amendment 1: 2013

Authorized Signatory:

Tokyo, Japan/ 5 April 2021

Place and date of issue


Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division

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Product Name and Model Name: Recorder Module WS-371P
Interface QI-371P
Interface QI-372P

Classification: IIa

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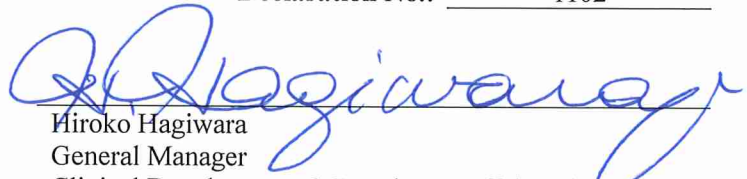
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Declaration No.: 1102

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