

Declaration No.:	3043	
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EU/RE DIRECTIVE DECLARATION OF CONFORMITY

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:

Business Address:

NIHON KOHDEN CORPORATION

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:

ELECTROCARDIOGRAPH

ECG-3350

Notified Body's Name and No.:

UL Japan, Inc., No.1731(Module B)

EU-Type examination Certificate

No.:

ULAR2107111

Standard Applied:

IEC 60601-1: 2005

IEC 60601-1 Amendment 1: 2012

IEC 60601-2-25: 2011

IEC 60601-2-25:1993+A1:1999 EN 60601-2-25:1995+A1:1999

IEC 60601-1-2: 2014 EN 300 328 V2.2.2 EN 301 893 V2.1.1 EN 62311: 2008

Authorized Signatory:

Tokyo, Japan / 30 July 2021

Place and date of issue

Hiroko Hagiwara General Manager

Clinical Development & Regulatory Affairs Division



Declaration No.:	1149
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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:

ELECTROCARDIOGRAPH

ECG-3350

SOFTWARE KIT

OS-335EK

Classification:

IIa

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: 2014 IEC 60601-1-6: 2010

IEC 60601-1-6 Amendment 1: 2013

IEC 60601-2-25: 2011 IEC 62133: 2002 IEC 62304:2015 IEC 62366: 2007

IEC 62366 Amendment 1: 2014

IEC 62366-1: 2015 EN 1041: 2008

EN 1041 Amendment 1: 2013

Authorized Signatory:

Tokyo, Japan / 18 June 2020

Place and date of issue

Hiroko Hagiwara

General Manager

Clinical Development & Regulatory Affairs Division



Declaration No.:	20165

RoHS DECLARATION OF CONFORMITY

This is a declaration made in accordance with the requirements of Council Directive 2011/65/EU of 8 June 2011 and 2015/863/EU of 31 March 2015 concerning the restriction of the use of certain hazardous substances in electrical and electronic equipment.



Manufacturer's Name:

NIHON KOHDEN CORPORATION

Business Address:

1-31-4 Nishiochiai, Shinjuku-ku, Tokyo 161-8560, Japan

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 2015/863/EU for ten regulated substances listed below.

Product Name(s):

ELECTROCARDIOGRAPH

ECG-3350

SOFTWARE KIT

QS-335EK

List of environmentally hazardous substances:

- 1) Lead
- 2) Mercury
- 3) Cadmium
- 4) Hexavalent Chromium
- 5) Polybrominated biphenyls (PBB)
- 6) Polybrominated diphenyl ethers (PBDE)
- 7) Bis(2-ethylhexyl) phthalate (DEHP)
- 8) Butyl benzyl phthalate (BBP)
- 9) Dibutyl phthalate (DBP)
- 10) Diisobutyl phthalate (DIBP)

Harmonised Standards Applied: EN 50581:2012

Authorised Signatory:

Tokyo, Japan/ 10 May 2021

Place and date of issue

Hiroko Hagiwara General Manager

Clinical Development & Regulatory Affairs Division