

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: Transmitter ZS-640P

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

EU-Type examination Certificate No.: 172140155/AA/00

Standard Applied: IEC 60601-1: 2005
IEC 60601-1 Amendment 1: 2012
IEC 60601-1-2: 2007
EN 300 220-1 V3.1.1
EN 300 220-2 V3.1.1

Authorized Signatory:

Tokyo, Japan / 19 May 2017
Place and date of issue



Masato Semba
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: Transmitter ZS-640P
Software Kit QS-113PG

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
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 60601-2-27: 2011
IEC 60601-2-49: 2011
IEC 80601-2-30: 2009
IEC 80601-2-30 Amendment 1: 2013
IEC 62304: 2006
IEC 62366: 2007
IEC 62366 Amendment 1: 2014
ISO 80601-2-61: 2011
EN 1041: 2008
EN 1041 Amendment 1: 2013
EN ISO 15223-1: 2016

Authorized Signatory:
Tokyo, Japan / 25 June 2020
Place and date of issue



Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division

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) : Transmitter ZS-640P

List of environmentally hazardous substances:

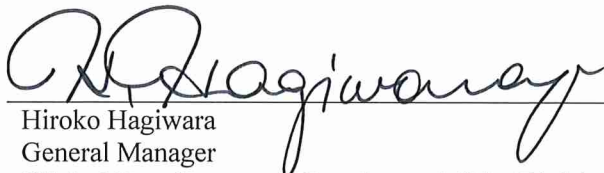
- 1) Lead
- 2) Mercury
- 3) Cadmium
- 4) Hexavalent Chromium
- 5) Polybrominated biphenyls (PBB)
- 6) Polybrominated diphenyl ethers (PBDE)
- 7) Bis(2-ethylhexyl) phthalate (DEHP)
- 8) Butyl benzyl phthalate (BBP)
- 9) Dibutyl phthalate (DBP)
- 10) Diisobutyl phthalate (DIBP)

Harmonised Standards Applied: EN 50581:2012

Authorised Signatory:

Tokyo, Japan/ 27 May 2021

Place and date of issue



Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division