

**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 ZM-540P


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

**EU-Type examination Certificate No.:** 172140477/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  
EN 62479: 2010

**Authorized Signatory:**

Tokyo, Japan / 23 June 2017  
Place and date of issue

  
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Masato Semba  
General Manager  
Quality Management Division

## 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:** Transmitter ZM-540P  
Software Kit QS-107P

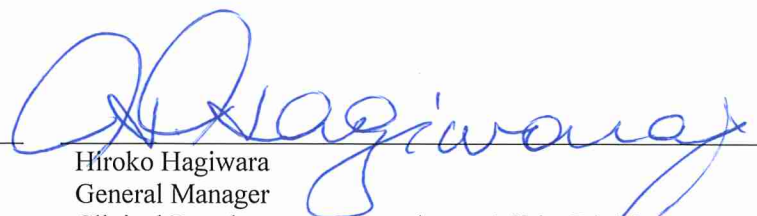
**Classification:** IIb

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  
EN 1041: 2008  
EN 1041 Amendment 1: 2013  
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 62304: 2006  
IEC 62366: 2007  
IEC 62366 Amendment 1: 2014  
IEC 80601-2-30:2009  
IEC 80601-2-30 Amendment 1:2013  
ISO 80601-2-61:2011  
ISO 10993-1:2009

**Authorized Signatory:**  
Tokyo, Japan / 5 April 2021  
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 ZM-540P

**List of environmentally hazardous substances:**

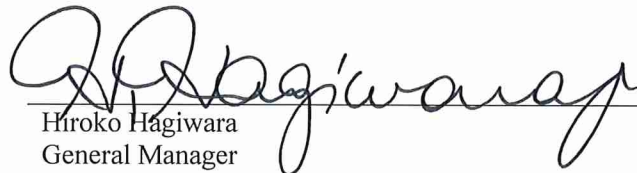
- 1) Lead
- 2) Mercury
- 3) Cadmium
- 4) Hexavalent Chromium
- 5) Polybrominated biphenyls (PBB)
- 6) Polybrominated diphenyl ethers (PBDE)
- 7) Bis(2-ethylhexyl) phthalate (DEHP)
- 8) Butyl benzyl phthalate (BBP)
- 9) Dibutyl phthalate (DBP)
- 10) Diisobutyl phthalate (DIBP)

**Harmonised Standards Applied:** EN 50581:2012

**Authorised Signatory:**

Tokyo, Japan/ 271 May 2021

Place and date of issue



Hiroko Hagiwara  
General Manager  
Clinical Development & Regulatory Affairs Division