NIHON KOHDEN

Declaration No.: 3028

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.

CE

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

Masato Semba
General Manager
Quality Management Division

様式 RE4

NIHON KOHDEN

Declaration No.: 1124

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).

CE
2797

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

MDD7-3A

NIHON KOHDEN

Declaration No.: 20118

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.

CE

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

MDA0023-4