NIHON KOHDEN

Declaration No.: 1077

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:	SpO2 Probe	TL-271T
	SpO2 Probe	TL-272T
	SpO2 Probe	TL-273T
	SpO2 Probe	TL-274T
	SpO2 Probe	TL-271T3
	SpO2 Probe	TL-272T3
	SpO2 Probe	TL-273T3
	SpO2 Probe	TL-274T3

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
ISO 10993-1: 2009
ISO 80601-2-61: 2017
IEC 60601-1: 2005
IEC 60601-1 Amendment 1: 2012
IEC 60601-1-6: 2010
IEC 60601-1-6 Amendment 1: 2013
IEC 62366: 2007
IEC 62366 Amendment 1: 2014
EN 1041: 2008
EN 1041 Amendment 1: 2013
EN ISO 15223-1: 2016

Note:
The underlined standard above is updated in this Declaration of Conformity.
Although the Declaration is issued after 26 May 2021, the Date of Application of MDR, the Declaration is made for the changes which do not correspond to significant changes specified in the MDCG 2020-3, and maintains compliance with the old standards listed on the Declaration dated 15 March 2019.
Consequently, this Declaration does not deviate from the MDR Article 120, and does not invalidate the Declaration of 15 March 2019.

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Authorized Signatory:

Tokyo, Japan / 18 February 2022
Place and date of issue

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