NIHON KOHDEN

Declaration No.: 1121

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).

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:		
	CO2 Sensor Kit	TG-980P
	CO2 Sensor Kit	TG-981T
	CO2 Sensor Kit	TG-981T1
	CO2 Sensor Kit	TG-981T4
	NPPV cap-ONE MASK SET L	VM-330Z
	NPPV cap-ONE MASK SET M	VM-331Z
	NPPV cap-ONE MASK SET S	VM-332Z
	NPPV cap-ONE MASK SET XS	VM-333Z
	cap-ONE MASK CUSHION L	VA-330Z
	cap-ONE MASK CUSHION M	VA-331Z
	cap-ONE MASK CUSHION S	VA-332Z
	cap-ONE MASK CUSHION XS	VA-333Z
	NPPV MASK FRAME	VA-380Z
	NPPV MASK HEADGEAR	VA-381Z

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
ISO 10993-1: 2009
ISO 80601-2-55: 2011
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 62304: 2015
IEC 62366: 2007
IEC 62366 Amendment 1: 2014
EN 1041: 2008
EN 1041 Amendment 1: 2013

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EN 13544-2: 2002
EN 13544-2 Amendment 1: 2009

Authorized Signatory:

Tokyo, Japan / 20 May 2021
Place and date of issue

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