NIHON KOHDEN

Declaration No.: 2033

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:		
	CO2 Sensor Kit	TG-900P
	CO2 Sensor Kit	TG-901T
	CO2 Sensor Kit	TG-901T3
	CO2 Sensor	TG-101T
	CO2 Sensor	TG-101TW
	CO2 Adapter	JG-900P
	CO2 Adapter	JG-901T
	CO2 Adapter	JG-901T3

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 80601-2-55: 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: 2006
IEC 62366: 2007
IEC 62366 Amendment 1: 2014
EN 1041: 2008
EN 1041 Amendment 1: 2013
EN ISO 15223-1: 2016

NIHON KOHDEN

Declaration No.: 2033

Authorized Signatory:

Tokyo, Japan / 16 April 2021
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division