NIHON KOHDEN

Declaration No.: 1099

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

Digitally signed by Moraru Marin
Date: 2021.0[illegible]
Reason: MoldSign Signature
Location: Moldova

Product Name and Model Name:	
MULTIGAS UNIT	GF-210R
MULTIGAS/FLOW UNIT	GF-220R
Software Kit	QS-069P

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
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 62304: 2006
IEC 62366: 2007
IEC 62366 Amendment 1: 2014
ISO 80601-2-55: 2011
ISO 10993-1: 2009
EN 1041: 2008
EN 1041 Amendment 1: 2013
EN ISO 15223-1: 2016

Authorized Signatory:
Tokyo, Japan / 15 March 2019
Place and date of issue

Yoshiyuki Fujita
General Manager
Quality Management Division

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European Representative:	NIHON KOHDEN EUROPE GmbH
Address:	Raiffeisenstrasse 10, D - 61191 Rosbach, Germany

Product Name and Model Name:

Flow adapter	TF-120P
Flow tube	YF-120P
Connection cable	YJ-600P
Connection cable	YJ-601P
Watertrap	YG-600P
Sampling line	YG-610P
Straight T-piece	YG-620P
Elbow T-piece	YG-621P
Mount adapter	DH-220P
Wall mount adapter	DH-221P
Unit hanger	DH-222P
Unit mount	DH-223P
Mount adapter	DH-230P
Connection cable	YJ-602P

Classification: I

Each kind of medical device complies with the applicable provisions of the essential requirements, the classification rules before being supplied.

Standard Applied:

EN ISO 13485: 2016
EN ISO 14971: 2012
IEC 60601-1: 2005
IEC 60601-1 Amendment 1: 2012
IEC 60601-1-2: 2007
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