	AQ-0002	Rev. 00	DATA REVISIONE:	01/04/2020
	Preparazione:	QA	Approvazione:	GM

EU Declaration of Conformity

Manufacturer:	**3A HEALTH CARE S.r.l.**
Address:	Via Marziale Cerutti, 90F/G 25017 Lonato del Garda (BS) Italy
SRN:	IT-MF-000009298
Product Category:	Accessories for aerosoltherapy equipment
Product Description:	Mouthpiece Set for C28P
Model (code):	NEB6027
Basic UDI-DI:	803371701NEB6204244
UDI-DI/EAN:	4015672112926
Classification for MDR:	Class IIa (MDR Annex VIII Rule 12)
Product Category for RoHS:	Category 8 (Medical devices)

We, 3A HEALTH CARE S.r.l., herewith declare, under our sole responsibility, that the above mentioned product meets the provisions of the following European Union Regulations, Council Directives and Standards. All supporting documentation is retained at the premises of the manufacturer. This Declaration of Conformity is valid in connection with the shipping inspection reports for the respective batch of produced devices.

General applicable regulations:	Medical Devices Regulation 2017/745
Standards:	EN 1041:2008+A1:2013 EN 13544-1:2007+A1:2009 IEC 62366-1:2015 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2021 EN ISO 10993-11:2017 EN ISO 10993-12:2021 EN ISO 10993-23:2021 EN ISO 18562-1:2017 EN ISO 13485:2016/A11:2021 EN ISO 14971:2019 EN ISO 15223-1:2021
Notified Body:	IMQ S.p.A.
Address:	Via Quintiliano 43 – 20138 Milano Italy
ID No:	Notified under number 0051 to the EC Commission
Certification Registration No:	Annex IX: 010/MDR

General applicable directives:	RoHS Directive 2011/65/EU
Standards:	EN 50581:2012

Place / Date	Lonato del Garda, 2023/06/20
Signature:	
Name:	Simone Abate
Position:	Quality Assurance & Regulatory Affairs Director

3A HEALTH CARE S.r.l.
Via Marziale Cerutti, 90F/G
25017 Lonato del Garda (BS) - Italy
Tel. +39 030 9133177 - Fax +39 030 9919114
Codice Fiscale e Partita IVA 03262640984

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