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:	Aerosoltherapy equipment
Product Description:	Compressor Nebulizer
Model (code):	C102 Total (NE-C102-E)
Basic UDI-DI:	803371701NEB354574R
UDI-DI/EAN:	4015672111219
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 EN 60601-1:2006/A11:2011/A1:2013 EN 60601-1-2:2015 EN 60601-1-6:2010+A1:2015 EN 60601-1-11:2015 IEC 62366-1:2015 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2021 EN ISO 10993-12:2021 EN ISO 10993-23:2021 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

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Codice Fiscale e Partita IVA 03262640984

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