

	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:** Adult Mask  
**Model (code):** NEB6007  
**Basic UDI-DI:** 803371701NEB6204244  
**UDI-DI/EAN:** 4015672110762  
**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.

<b>General applicable regulations:</b>	Medical Devices Regulation 2017/745
<b>Standards:</b>	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 10993-12:2021 EN ISO 10993-23:2021 EN ISO 13485:2016/A11:2021 EN ISO 14971:2019 EN ISO 15223-1:2021
<b>Notified Body:</b>	IMQ S.p.A.
<b>Address:</b>	Via Quintiliano 43 – 20138 Milano Italy
<b>ID No:</b>	Notified under number 0051 to the EC Commission
<b>Certification Registration No:</b>	Annex IX: 010/MDR

<b>General applicable directives:</b>	RoHS Directive 2011/65/EU
<b>Standards:</b>	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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