EU Declaration of Conformity

Manufacturer:	**3A HEALTH CARE S.r.l.**
Address:	Via Marziale Cerutti, 90F/G
SRN:	IT-MF-000009298
Product Category:	Accessories for aerosoltherapy equipment
Product Description:	Child Mask for C28P
Model (code):	NEB6028
Basic UDI-DI:	803371701NEB6204244
UDI-DI/EAN:	4015672112933
Intended purpose:	This product is intended to be used for inhaling medication for respiratory disorders. This product is single-patient reuse.

Classification for MDR: Class IIa (MDR Annex VIII Rule 12)

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 ISO 20417:2021	EN ISO 18562-1:2020
	EN 62366-1:2015/A1:2020	EN ISO 18562-2:2020
	EN ISO 27427:2023	EN ISO 18562-3:2020
	EN ISO 10993-1:2018	EN ISO 18562-4:2020
	EN ISO 10993-5:2009	EN ISO 14971:2019/A11:2021
	EN ISO 10993-10:2021	EN ISO 15223-1:2021
	EN ISO 10993-12:2021	EN ISO 13485:2016/A11:2021
	EN ISO 10993-23:2021	--
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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 (chapters I and III): 010/MDR	

General applicable directives:	RoHS Directive 2011/65/EU, 2015/863/EU, 2017/2102/EU
Product Category for RoHS:	Category 8 (Medical devices)
Standards:	EN IEC 63000:2018

Place / Date Lonato del Garda (BS) 08/06/2026

Signature:

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