

# Konformitätserklärung/ Declaration of Conformity

Wir der Hersteller/We the manufacturer:

**Akzenta International SA**  
**Via Giuseppe Motta 24**  
**6830 Chiasso**  
**Switzerland**  
**CHRN:CHRN-MF-20001985**  
**SRN: CH-MF-000036434**

**EU REP DATA :**  
**IQX GMBH**  
**Kudlichstraße 37**  
**4020 Linz, Austria – SRN: AT-AR-000016713**

Declare that the product **PRIME|ONE COOL BREATH FACE MASKS** with article number **beginning with FAMDA25-AKZ** satisfies the requirements laid down in General Safety and Performance Requirements of Medical Device Regulation (EU) 2017/745.

We, moreover, declare and guarantee that :

- The above mentioned product is conform to the Medical Device Regulation EU REG. 2017/745 – MEDICAL DEVICE belonging to CLASS 1 according to rule 1
- The above mentioned product is conform to EN 14683:2019
- The above mentioned product is conform to EN ISO 14971:2019
- The above mentioned product is conform to EN ISO 15223-1:2021 and ISO 20417:2021
- The above mentioned product is conform to ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2010

**PRIME|ONE COOL BREATH FACE MASKS | TYPE IIR**  
**BASIC UDI-DI : 42504766FAMTD**

The intended use of this medical devices is to be worn by healthcare professionals during medical activities and by lay users during any daily activity in the private sector in order to avoid the dispersion of pathogens (e.g. bacteria or viruses) dispersed in liquid droplets and aerosols.



**A. Amedeo Missfeldt**  
Regulatory Affairs

21/03/2025

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