

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 PERFECT FIT facemasks - with article number beginning with FAMPA25-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 n°1
- The above mentioned product is conform to EN 14683:2019+AC: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 EN ISO 20417:2021
- The above mentioned product is conform to EN ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2010

PRIME|ONE PERFECT FIT | TYPE IIR
BASIC UDI-DI : 42504766FAMTD

The intended use of this medical device 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.


Amedeo Missfeldt
Regulatory Affairs

10/10/2024

Date