

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 **TOP MASK ULTRASAFE – with article number beginning with FAMAA24-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, ISO 20417:2021
- The above mentioned product is conform to EN ISO 10993-1:2018/10993-5:2009/10993-10:2013

TOP MASK ULTRASAFE | TYPE IIR
BASIC UDI-DI : 42504766FAMTD

The intended use of this medical devices is to to be used by medical and nursing staff to protect the patient during operations performed in the dental and medical field.


A. Amedeo Missfeldt
Regulatory Affairs

31/07/2023

Date