

# 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 products **STERILISATION REELS/POUCHES – with article numbers beginning with STPAA26-AKZ/ STRAA26-AKZ** satisfy 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 I
- The above mentioned product is conform to EN 868-2:2017 ( App. B/D and E), EN 868-5:2018, EN ISO 11607-1:2019, EN ISO 11607-2:2019, EN ISO 11140-1:2014.
- The above mentioned product is conform to EN ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 10993-12:2021.
- The above mentioned product is conform to EN ISO 15223-1:2021 and EN ISO 20417:2021, EN ISO 14971:2019.

**STERILISATION REELS/POUCHES**  
**BASIC UDI-DI : 42504766STAB**

The medical device has been designed and manufactured to be used in medical facilities to wrap and sterilize instruments or other medical devices with saturated steam and Ethylene Oxide EO.

  
**A. Amedeo Missfeldt**  
Regulatory Affairs

13/06/2024

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Date