AKZENTA
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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.

13/06/2024

Date

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i.A. Amedeo Missfeldt
Regulatory Affairs

Tel.: +41 (0) 91 921 14 92
Web: akzenta.com
Mail: business@akzenta.com

Visit us at
akzenta.com

USt. ID Nr. DE815221533
VAT No. CHE-337.693.284 IVA
Company No CHE-337.693.284

General Manager: Dr. Joachim Missfeldt

Akzenta International SA