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 MICRO APPLICATORS -with article number beginning with MICAP25-AKZ** satisfies the requirements laid down in the 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 5 Annex VIII
- The above mentioned product is conform to EN ISO 10993-1:2025, EN ISO 10993-5:2009, EN ISO 10993-10:2010
- The above mentioned product is conform to EN ISO 14971:2019/A11:2021
- The above mentioned product is conform to EN ISO 15223-1:2021/Amd 1:2025 and EN ISO 20417:2021

PRIME|ONE MICRO APPLICATORS
BASIC UDI-DI : 42504766MICUL

The intended use of this product is to be used by dental professionals to accurately apply a product/substance/material onto the teeth of a patient.

This Declaration of Conformity is issued in accordance with Annex IV of Regulation (EU) 2017/745.

i.A. Amedeo Missfeldt
Regulatory Affairs

04.03.2026

Date

Tel.
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