

Konformitätserklärung/ Declaration of Conformity

Wir der Hersteller/We the manufacturer

Akzenta International SA

Via Giuseppe Motta 24

6930 Chiasso

Switzerland

CHRN:CHRN-MF-20001985

EU REP DATA :

IQX GMBH

Kudlichstraße 37

4020 Linz, Austria – SRN: AT-AR-000016713

Declare that the product **TOP TOUCH PLUS NITRILE GLOVES** 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
- The above mentioned product is conform to UNI CEI EN ISO 15223-1:2017
- The above mentioned product is conform to UNI CEI EN 1041:2013
- The above mentioned product is conform to UNI CEI EN 14971:2020, EN 16523-1:2015
- The above mentioned product is conform to EN 455 part 1,2,3 and 4, EN 420
- The above mentioned product is conform to EU REG. 2016/425 and conform to EN 374 part 1,2,4 and 5
- The above mentioned product is conform to EN ISO 10993-5,10

TOP TOUCH PLUS NITRILE GLOVES

BASIC UDI : 42504766GLOUP


F.A. Amedeo Missfeldt
Regulatory Affairs

16.01.2023

Date