

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 **EXTRA GRIP LATEX GLOVES GLOCL29-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
- The above mentioned product is conform to UNI CEI EN ISO 15223-1:2017
- The above mentioned product is conform to UNI CEI EN 1041:2008+A1:2013
- The above mentioned product is conform to UNI CEI EN 14971:2020, EN 16523-1:2015, ISO 13485:2016, EN 420:2003+A1:2009
- The above mentioned product is conform to EN 455 part 1,2,3 and 4
- 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 10993-1,5,10 and EN ISO 21420:2020
- The above mentioned product is conform to ASTM D3578:2019, ASTM D7161:2016, ASTM D7160:2016, ASTM F1671:2013,

EXTRA GRIP LATEX GLOVES
BASIC UDI : 42504766GLOUP


F.A. Amedeo Missfeldt
Regulatory Affairs

01-01-2022

Date