

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 EXTRA GRIP LATEX GLOVES – with article number beginning with GLOCL60-AKZ-WH** 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 according to rule 01
- The above mentioned product is conform to EN ISO 15223-1:2021/Amd. 1:2025, EN ISO 20417:2021, EN ISO 14971:2019/A11:2021
- The above mentioned product is conform to EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2015, EN 455-4:2009
- The above mentioned product is conform to EU REG. 2016/425 – PPE equipment of Cat. III and conform to EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN ISO 21420:2020 and EN 16523-1:2015+A1:2018
- The above mentioned product is conform to EN ISO 10993-1:2025, EN ISO 10993-5:2009, EN ISO 10993-10:2010

PRIME|ONE EXTRA GRIP LATEX GLOVES
BASIC UDI-DI : 42504766GLOUP

The intended use of this product is to be worn by health professionals during medical activities, or to be worn by other users and in other environments, in order to avoid contamination towards the patient and other people.

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


F.A. Amedeo Missfeldt
Regulatory Affairs

09.12.2025

Date