

Konformitätserklärung/ Declaration of Conformity

Wir der Hersteller/We the manufacturer

Akzenta International SA
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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 OAT COATED NITRILE GLOVES –with article number beginning with GLOBN53-AKZ-DW** 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 n°1
 - The above mentioned product is conform to EU REG. 2016/425 -Cat. III PPE and conform to EN ISO 374-1:2016+A1:2018, EN ISO 374-4:2019, EN ISO 374-5: 2016, EN ISO 21420:2020, ISO 16604:2004, EN 16523-1:2015+A1:2018
 - The above mentioned product is conform to EN 455 part 1:2000,EN 455-2:2015,EN 455-3:2015, EN 455-4:2009, EN ISO 14971:2020, EN ISO 15223-1:2021/Amd1:2025
 - The above mentioned product is conform to EN ISO 10993-1:2021, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 10993-11: 2018
- The above mentioned product is moreover conform to: ISO 2859-1:1999/Amd1:2011, ASTM D6319, ASTM D7160

PRIME|ONE OAT COATED NITRILE 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.


J.A. Amedeo Missfeldt
Regulatory Affairs

23.05.2025

Date