

Konformitätserklärung/ Declaration of Conformity

Wir der Hersteller/We the manufacturer:

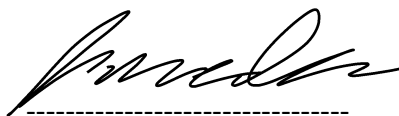
Akzenta International SA
Via Giuseppe Motta 24
6930 Chiasso
Switzerland

Declare that the product **STYLE 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
- 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

STAYLE NITRILE GLOVES
BASIC UDI : 42504766GLOUP



Amedeo Missfeldt
Regulatory Affairs

01-01-2022

Date