

EU DECLARATION OF CONFORMITY

The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM

declares under his sole responsibility, that the PPE described hereafter:

BioClean™ Nitrile RABS/Isolator Sleeve/Glove System GSG10NIT80

Products manufactured as of: [2023/07/26]

PPE to be used against category III risks

EN ISO 374-1:2016
Type B



KPT

EN 421



EN ISO 374-5



VIRUS

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 21420:2020, EN ISO 374-1:2016, EN 421:2010, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2023/0466, issued by the Notified Body:

**CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM**

and is subject to the procedure set out in Annex VIII (Module D) of the Regulation under the supervision of the Notified Body:

**CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM**



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2023/07/26

EU DECLARATION OF CONFORMITY

The Manufacturer
NITRITEX (M) SDN BHD,
NO.2, JALAN JURUNILAI U1/20,
SEKSYEN U1, HICOM GLENMARIE
INDUSTRIAL PARK,
40150 SHAH ALAM,
SELANGOR, MALAYSIA

and authorized representative:
NITRITEX LTD
UNIT 4, MINTON ENTERPRISE PARK
OAKS DRIVE, NEWMARKET
SUFFOLK, CB8 7YY, UK

declare under their sole responsibility, that the PPE described hereafter:

BioClean Sterile Sleeve Glove system, Polychloroprene Size 8 glove GSGxxNIT80

Products manufactured till: [2023/07/25]

PPE to be used against category III risks



EN ISO 374-1:2016
Type B



KPT

EN ISO 374-5



VIRUS

2016

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 421:2010, EN ISO 374-1:2016 Type B, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 060/2019/1034, issued by the Notified Body:

CENITEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VIII (Module D) of the Regulation under the supervision of the Notified Body:

SGS FIMKO OY (0598)
TAKOMOTIE 8,
FI-00380 HELSINKI,
FINLAND



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2019/06/03