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™ Non-Sterile Nitrile RABS/Isolator Glove CGL10NIT59

Products manufactured as of: [2019/06/04] and till: [2028/07/25]

PPE to be used against category III risks

EN388: 2016



4101X



AJKNOTS



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN 421:2010, EN ISO 21420:2020, EN ISO 374-1:2016, 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 032/2023/0462, 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: 2023/07/25

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 Non-Sterile, Clean Nitrile 5 finger glove CGLxxNIT59

Products manufactured till: [2019/06/03]

PPE to be used against category III risks









is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016, EN 420:2003 + A1:2009, EN 421:2010, EN ISO 374-1:2016, 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 060/2019/1025, 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:

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

Guido Van Duren Director - Regulatory affairs Ansell

Place: Brussels Date: 2019/06/03