# **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<br/>Glove CGL36NIT59Products manufactured as of: [2028.07.26]PPE to be used against category III risksENSBE: 2016Image: Dispersive Colspan="2">Image: Dispersive Colspan="2" Image: Dispe

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 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 032/2024/0182, 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

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Guido Van Duren Director - Regulatory affairs Ansell

Place: Brussels Date: 2024.03.19

# **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:



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:

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CENTEXBEL (0493) TECHNOLOGIEPARK 70 B-9052 ZWIJNAARDE BELGIUM

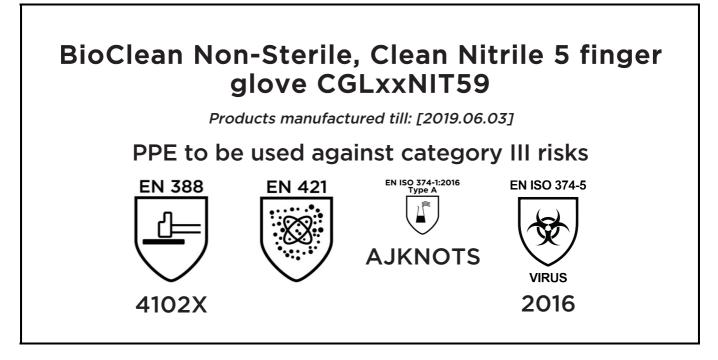
Guido Van Duren Director - Regulatory affairs Ansell

Place: Brussels Date: 2024.03.18

### **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:



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016, 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