# EU DECLARATION OF CONFORMITY

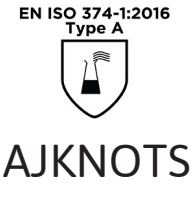
The Manufacturer
**ANSELL HEALTHCARE EUROPE N.V.**
**RIVERSIDE BUSINESS PARK, BLOCK J**
**BOULEVARD INTERNATIONAL 55**
**B-1070 BRUSSELS**
**BELGIUM**

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

## BioClean™ Sterile & Clean Nitrile Isolator Glove GGL10NIT59

*Products manufactured as of: [2024/03/19]*

PPE to be used against category III risks







is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016, EN ISO 374-5:2016, EN 388:2016 +A1:2018, EN 421:2010 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2024/0181, 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: 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:

## BioClean™ Sterile & Clean Nitrile Isolator Glove GGL10NIT59

*Products manufactured as of: [2023/07/25] and till: [2024/03/18]*

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 +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 032/2023/0461, 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: 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 Sterile Nitrile 5 finger glove GGLxxNIT59

*Products manufactured till: [2023/07/24]*

PPE to be used against category III risks


is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 421:2010, EN ISO 374-5:2016, EN ISO 374-1:2016, EN 388:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 060/2019/1024, 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