

# 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 Mitten CGL30NITM9

*Products manufactured as of: [2024/06/04] and till: [2028/07/25]*

PPE to be used against category III risks

EN388: 2016



4101X

EN 421



EN ISO 374-1:2016  
Type A



AJKNOTS

EN ISO 374-5



VIRUS

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 032/2023/0464, 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 Notified Body:



Guido Van Duren  
Director - Regulatory affairs  
Ansell

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

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 mitten CGLxxNITM9

*Products manufactured till: [2024/06/03]*

PPE to be used against category III risks

EN 388



4101X

EN 421



EN ISO 374-1:2016  
Type A



AJKNOT

EN ISO 374-5



VIRUS

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 060/2019/1029, issued by the Notified Body:

CENTEXBEL (0493)  
TECHNOLOGIEPARK 70  
B-9052 ZWIJNAARDE  
BELGIUM

the procedure set out in Annex VIII (Module D) of the Regulation under the  
Notified Body:

Guido Van Duren  
Director - Regulatory affairs  
Ansell  
SGS FIMKO OY (0598)  
TAKOMOTIE 8,  
FI-00380 HELSINKI,  
FINLAND

Place: Brussels  
Date: 2019/06/03