

# 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: [2024/06/04] and till: [2028/07/26]*

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

and authorized representative:  
NITRITEK 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: [2024/06/03]*

PPE to be used against category III risks



EN ISO 374-1:2016  
Type B



KPT

EN ISO 374-5



VIRUS

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 420:2003 + A1:2009, 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:

**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