

# 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**



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**