

# 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 Synergy BSAN Non-sterile Nitrile Cleanroom Gloves**

*Products manufactured till: [2027/12/23]*

**PPE to be used against category III risks**



**KPT**



**VIRUS**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards 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 032/2022/1082, 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: 2022/12/23**

# EU DECLARATION OF CONFORMITY

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

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

## **BioClean Synergy BSAN Non-sterile Nitrile Gloves**

**PPE to be used against category III risks**

**EN 421**



**EN ISO 374-5**



**VIRUS**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards 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 060/2019/0182, 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:

**SGS FIMKO OY (0598)**  
**TAKOMOTIE 8,**  
**FI-00380 HELSINKI,**  
**FINLAND**

**Guido Van Duren**  
**Director - Regulatory affairs**  
**Ansell**

**Place: Brussels**  
**Date: 2019/04/01**