

# EU DECLARATION OF CONFORMITY

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

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

## BioClean™ Legacy BLA2 Non-sterile Latex Cleanroom Glove

*Products manufactured as of: [2024/12/11]*

PPE to be used against category III risks



**K P T**



**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+A1:2018, 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 032/2024/0713, 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: 2024/12/11

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BOULEVARD INTERNATIONAL 55  
B-1070 BRUSSELS  
BELGIUM  
**WWW.ANSELL.COM**

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

## BioClean™ Legacy BLA2 Non-sterile Latex Cleanroom Glove

*Products manufactured as of: [2024/07/16] and till: [2024/12/10]*

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 21420:2020, EN ISO 374-5:2016, EN ISO 374-1:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2023/0011, issued by the Notified Body:

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**BELGIUM**

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2024/07/16

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

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

## BioClean™ Legacy BLA2 Non-sterile Latex Cleanroom Glove

*Products manufactured as of: [2023/01/06] and till: [2024/07/15]*

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 21420:2020, EN ISO 374-5:2016, EN ISO 374-1:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2023/0011, 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: 2023/01/06

# 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 Legacy Non-sterile Latex Gloves BLA2

*Products manufactured till: [2023/01/05]*

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 420:2003 + A1:2009, 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 060/2018/1776, 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