

# 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™ Sterile Nitrile Isolator Sleeve GSL20NITPP26

*Products manufactured as of: [2024/03/19]*

PPE to be used against category III risks

EN388: 2016



4102X

EN ISO 374-1:2016  
Type A



AJKNOTS

EN ISO 374-5



VIRUS

EN 421



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 421:2010 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2024/0185, 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: 2024/03/19

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

## BioClean™ Sterile Nitrile Isolator Sleeve GSL20NITPP26

*Products manufactured till: [2024/03/18]*

PPE to be used against category III risks

EN388: 2016



4101X

EN 421



EN ISO 374-1:2016  
Type A



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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 032/2023/0465, issued by the Notified Body:

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A handwritten signature in black ink, appearing to read 'Guido Van Duren'.

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2023/07/25