

# UK 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

UK Importer  
PATIENT GUARD LTD  
LANCASTER HOUSE,  
AMY JOHNSON WAY,  
BLACKPOOL, LANCASHIRE,  
FY4 2RP, UNITED KINGDOM  
INFO@PATIENTGUARD.CO.UK

declare under their sole responsibility, that the PPE described hereafter:

## BioClean™ Sterile Nitrile RABS/Isolator Mitten GGL30NITM9

*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 2016/425 on personal protective equipment, as amended to apply in GB, 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 Type-examination (Module B, Annex V of the Regulation), under certificate number 032/2024/0183, issued by the Body:

**CENTEXBEL (0493)  
TECHNOLOGIEPARK 70  
B-9052 ZWIJNAARDE  
BELGIUM**

and is subject to the conformity assessment procedure set in out in Annex VIII (Module D) of the Regulation under the surveillance of the Approved Body:

Guido Van Duren  
Director - Regulatory affairs  
Ansell

**CENTEXBEL (0493)  
TECHNOLOGIEPARK 70  
B-9052 ZWIJNAARDE  
BELGIUM**

Place: Brussels  
Date: 2024/03/19

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

## BioClean™ Sterile Nitrile RABS/Isolator Mitten GGL30NITM9

*Applicable Until [2024/03/18]*

PPE to be used against category III risks

EN388: 2016



4101X

EN 421



EN ISO 374-1:2016  
Type A



AJKNOST

EN ISO 374-5



VIRUS

is in conformity with the provisions of Regulation 2016/425 on personal protective equipment, as amended to apply in GB, 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 Type-examination (Module B, Annex V of the Regulation), under certificate number 032/2023/0463, issued by the Body:

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Director - Regulatory affairs  
Ansell

**CENTEXBEL INTERNATIONAL LTD,  
8 NORTHUMBERLAND AVENUE,  
LONDON, WC2N 5BY,  
UK**

Place: Brussels  
Date: 2023/07/25