

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:

**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 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:

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 Body:

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



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2023/07/25