

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™ Prelude BPSL Sterile Latex Cleanroom Glove

Products manufactured as of: [2025/10/01]

PPE to be used against category III risks



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 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 032/2023/0014, 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 (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

Guido Van Duren
Director – Regulatory affairs
Ansell

Place: Brussels
Date: 2025/10/01

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

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

BioClean™ Prelude BPSL Sterile Latex Cleanroom Glove

Applicable Until [2025/09/30]

PPE to be used against category III risks



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 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 032/2023/0014, 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 (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

Guido Van Duren
Director – Regulatory affairs
Ansell

Place: Brussels
Date: 2023/01/06