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

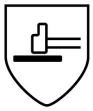
declare under their sole responsibility, that the PPE described hereafter:

HyFlex™ 11-501

Products manufactured as of: [2026/09/17]

PPE to be used against category II risks

EN388: 2016



3X41D

EN 407

X1XXXX

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, EN407:2020 , EN ISO 21420:2020+A1:2024 and is identical to the PPE which is subject to the Type-examination (Module B, Annex V of the Regulation), under certificate number 032/2026/0492, issued by the Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the conformity assessment procedure set out in Annex VI (Module C) of the Regulation.

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2026/09/17

UK DECLARATION OF CONFORMITY

The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
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BLACKPOOL, LANCASHIRE,
FY4 2RP, UNITED KINGDOM
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declare under their sole responsibility, that the PPE described hereafter:

HyFlex® 11-501

Applicable Until [2026/09/16]

PPE to be used against category III risks

EN388: 2016

3X41D

EN 407

X1XXXX

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, EN407:2020 , EN ISO 21420:2020 and is identical to the PPE which is subject to the UK Type-examination (Module B, Annex V of the Regulation), under certificate number AB0321/23777-01/E00-00, issued by the Approved Body:

SATRA TECHNOLOGY CENTRE (0321)
WYNDHAM WAY, TELFORD WAY,
KETTERING, NORTHAMPTONSHIRE,
NN16 8SD, UNITED KINGDOM

and is subject to the conformity assessment procedure set out in Annex VII (Module C2) of the Regulation under the surveillance of the Approved Body:

SATRA TECHNOLOGY CENTRE (0321)
WYNDHAM WAY, TELFORD WAY,
KETTERING, NORTHAMPTONSHIRE,
NN16 8SD, UNITED KINGDOM

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2023/03/16