

UK DECLARATION OF CONFORMITY

El fabricante
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM

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

declara bajo su única responsabilidad que el EPI descrito a continuación:

HyFlex™ 11-318

Productos fabricados a partir de: [2026/03/24]

PPE to be used against categoría II risks

EN 16350



EN388: 2016



XX4XB

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 16350:2014, EN 388:2016 +A1:2018, EN ISO 21420:2020 and is identical to the PPE which is subject to the Type-examination (Module B, Annex V of the Regulation), under certificate number 032/2026/0149, issued by the Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

y está sujeto al procedimiento establecido en el anexo VI (módulo C) del Reglamento.

Guido Van Duren
Director - Regulatory affairs
Ansell

Lugar: Bruselas
Fecha: 2026/03/24

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El fabricante

**ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM**

declara bajo su única responsabilidad que el EPI descrito a continuación:

HyFlex® 11-318

Applicable Until [2026/03/23]

PPE to be used against categoría II risks

EN388: 2016



XX4XB

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 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 AB0321/24732-01/E00-00, issued by the Approved Body:

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

y está sujeto al procedimiento establecido en el anexo VI (módulo C) del Reglamento.

Guido Van Duren
Director - Regulatory affairs
Ansell

Lugar: Bruselas
Fecha: 2023/08/31