

# 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™ 11-318**

*Products manufactured as of: [2026/03/24]*

**PPE to be used against category 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**

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: 2026/03/24**

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**ANSELL HEALTHCARE EUROPE N.V.**  
**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**  
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declares under his sole responsibility, that the PPE described hereafter:

**HyFlex® 11-318**

*Applicable Until [2026/03/23]*

**PPE to be used against category 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**

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

A handwritten signature in black ink, appearing to read 'Guido Van Duren', written over a horizontal line.

**Guido Van Duren**  
**Director - Regulatory affairs**  
**Ansell**

**Place: Brussels**  
**Date: 2023/08/31**