

# EU 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:

**HyFlex™ 11-543**

*Products manufactured as of: [2026/06/04]*

**PPE to be used against category II risks**

**EN 16350**



**EN388: 2016**



**EN 407**



**4X32F**

**X1XXXX**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 16350:2014, EN 388:2016 +A1:2018, EN407:2020 , EN ISO 21420:2020 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2026/0311, issued by the Notified Body:

**CENTEXBEL (0493)**  
**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

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

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

**Place: Brussels**  
**Date: 2026/06/04**

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**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:

**HyFlex® 11-543**

*Products manufactured as of: [2024/06/25] and till: [2026/06/03]*

**PPE to be used against category II risks**

EN388: 2016



**4X32F**

EN 407



**X1XXXX**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 21420:2020, EN407:2020 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2023/0550.02, issued by the Notified Body:

**CENTEXBEL (0493)**  
**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

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

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

**Place: Brussels**  
**Date: 2024/06/25**

# EU 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:

**HyFlex® 11-543**

*Products manufactured till: [2024/06/24]*

**PPE to be used against category III risks**

EN388: 2016



**4X32F**

EN 407



**X1XXXX**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 21420:2020, EN407:2020 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2023/0550, issued by the Notified Body:

**CENTEXBEL (0493)**  
**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

**CENTEXBEL (0493)**  
**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

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

**Place: Brussels**  
**Date: 2023/08/28**