

# EU DECLARATION OF CONFORMITY

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

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

**HyFlex® 11-561**

*Products manufactured as of: [2024/12/05]*

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

EN388: 2016



**4X42C**

EN 407



**X1XXXX**

is in conformity with the provisions of Regulation (EU) 2016/425 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 EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2024/0705, 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: 2024/12/05**

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

**HyFlex<sup>®</sup> 11-561**

*Products manufactured as of: [2024/07/22] and till: [2024/12/04]*

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

EN388: 2016



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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: 2024/07/22**

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**BELGIUM**

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

**HyFlex<sup>®</sup> 11-561**

*Products manufactured as of: [2022/01/25] and till: [2024/07/21]*

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

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**4X42C**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, 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 032/2022/0065, issued by the Notified Body:

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Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2022/01/25

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*Products manufactured till: [2022/01/24]*

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



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 420:2003 + A1:2009, EN 388:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/1428, issued by the Notified Body:

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**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

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

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Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2019/09/20