

# 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<sup>®</sup> 11-939**

*Products manufactured as of: [2024/12/17]*

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

EN388: 2016



**4X42B**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 21420:2020, ISO 18889:2019 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2021/1340.02, 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**

A handwritten signature in black ink, appearing to read 'Guido Van Duren'.

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2024/12/17

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**ANSELL HEALTHCARE EUROPE N.V.**  
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**BELGIUM**

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

**HyFlex<sup>®</sup> 11-939**

*Products manufactured as of: [2021/12/17] and till: [2024/12/16]*

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

EN388: 2016



ISO 18889

**4X42B**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 21420:2020, ISO 18889:2019 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2021/1340, issued by the Notified Body:

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

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

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

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Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2021/12/17

# EU DECLARATION OF CONFORMITY

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**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

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

**HyFlex<sup>®</sup> 11-939**

*Products manufactured till: [2021/12/16]*

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



**4X42B**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards ISO 18889:2019, EN 388:2016, EN 420:2003 + A1:2009 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2020/0315, issued by the Notified Body:

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

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

**Place: Brussels**  
**Date: 2020/03/03**