

# 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:

**Edge® 48-216**

*Products manufactured as of: [2025/01/29]*

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

EN388: 2016



**4133B**

EN 407



**413X4X**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 12477:2001 + A1:2005, 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 032/2021/1104.02, 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**



Guido Van Duren  
Director – Regulatory affairs  
Ansell

Place: Brussels  
Date: 2025/01/29

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

## Edge® 48-216

*Products manufactured as of: [2021/11/09] and till: [2025/01/28]*

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

EN388: 2016



4133B

EN 407



413X4X

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 12477:2001 + A1:2005, 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 032/2021/1104, 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: 2021/11/09

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**BELGIUM**  
**WWW.ANSELL.COM**

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

## **EDGE® 48-216**

*Products manufactured as of: [2019/08/09] and till: [2021/11/08]*

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

**EN 388**



**4133B**

**EN 407**



**413X4X**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 420:2003 + A1:2009, EN 388:2016, EN 407:2004 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/1307, issued by the Notified Body:

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

Guido Van Duren  
Director – Regulatory affairs  
Ansell

Place: Brussels  
Date: 2019/08/09

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**EDGE® 48-216**

*Products manufactured till: [2019/08/08]*

PPE to be used against category III risks

EN 388



4133

EN 407



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is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2003, EN 420:2003 + A1:2009, EN 407:2004 and is identical to the PPE which is subject to the EC Type examination; under certificate number 032/2016/0148 issued by the Notified Body:

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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: 2016/02/16