

# 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:

**Edge<sup>®</sup> 48-140 ESD**

*Products manufactured as of: [2021/11/09]*

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

**EN 16350**



**EN388: 2016**



**3121A**

is in conformity with the provisions of Regulation (EU) 2016/425 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 EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2021/1169, 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: 2021/11/09**

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**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

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

**EDGE<sup>®</sup> 48-140**

*Products manufactured as of: [2021/01/25] and till: [2021/11/08]*

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

EN 16350



EN 388



3121A

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 16350:2014, 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 032/2021/0096, 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: 2021/01/25

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**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:

**EDGE<sup>®</sup> 48-140**

*Products manufactured as of: [2018/07/01] and till: [2021/01/24]*

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

EN 16350



EN 388



3121A

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 16350:2014, 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 032/2018/1113, 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: 2018/07/01

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**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

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

**EDGE<sup>®</sup> 48-140**

*Products manufactured till: [2018/06/30]*

**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 and is identical to the PPE which is subject to the EC Type examination; under certificate number 032/2016/0902 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: 2016/10/04