

# 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**

and authorized representative:  
**PATIENT GUARD LTD**  
**LANCASTER HOUSE,**  
**AMY JOHNSON WAY,**  
**BLACKPOOL, LANCASHIRE,**  
**FY4 2RP, UNITED KINGDOM**  
**INFO@PATIENTGUARD.CO.UK**

declare under their sole responsibility, that the PPE described hereafter:

**Edge® 48-920**

*Products manufactured as of: [2023/11/20]*

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

EN388: 2016



**4121A**

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 032/2021/0777.02, 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.

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: 2023/11/20**

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

**Edge® 48-920**

*Products manufactured as of: [2021/08/18] and till: [2023/11/19]*

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

EN388: 2016



**4121A**

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 032/2021/0777, issued by the Notified Body:

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Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2021/08/18

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**BOULEVARD INTERNATIONAL 55**  
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declares under his sole responsibility, that the PPE described hereafter:

**Edge®48-920**

*Products manufactured till: [2021/08/17]*

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



4121A

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards 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 032/2019/0287, 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: 2019/02/22