

# 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:

**AlphaTec<sup>®</sup> 58-535W**

*Products manufactured as of: [2024/06/06]*

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

**EN 407**



**X1XXXX**

**EN ISO 374-1:2016  
Type A**



**AJKLOPT**

**EN ISO 374-5:2016**



**EN388: 2016**



**3131A**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN407:2020 , EN ISO 374-1:2016, EN ISO 374-5:2016, EN 388:2016 +A1:2018 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2021/1190.02, 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: 2024/06/06**

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**BELGIUM**

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

## AlphaTec® 58-535W

*Products manufactured as of: [2021/11/15] and till: [2024/06/05]*

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

EN ISO 374-1:2016  
Type A



**AJKLOPT**

EN ISO 374-5:2016



EN388: 2016



**3131A**

EN 407



**X1XXXX**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016, EN ISO 21420:2020, EN ISO 374-5:2016, EN 388:2016 +A1:2018, 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 032/2021/1190, issued by the Notified Body:

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**B-9052 ZWIJNAARDE**  
**BELGIUM**

A handwritten signature in black ink.

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2021/11/15

# EU DECLARATION OF CONFORMITY

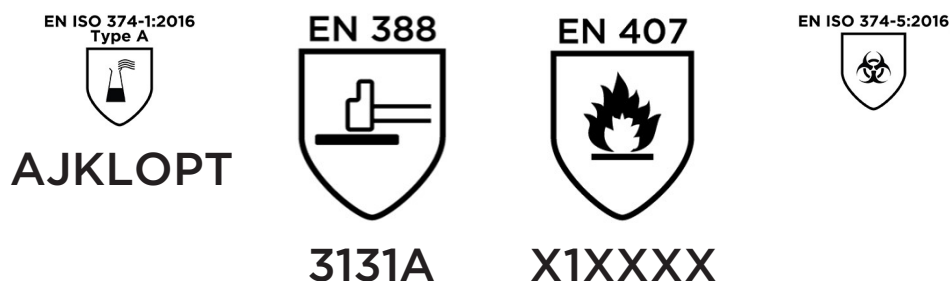
The Manufacturer  
**ANSELL HEALTHCARE EUROPE N.V.**  
**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

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

## AlphaTec® 58-535W

*Products manufactured as of: [2018/05/02] and till: [2021/11/14]*

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



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 420:2003 + A1:2009, EN ISO 374-1:2016, EN 388:2016, EN 407:2004, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2018/0804, 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: 2018/05/02

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**B-1070 BRUSSELS**  
**BELGIUM**

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

**AlphaTec<sup>®</sup> 58-535W**

*Products manufactured till: [2018/05/01]*

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

**EN 374**



**EN 388**



**4121**

**EN 374**



**JKL**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards , EN 388:2003, EN 420:2003 + A1:2009, EN 374:2003 and is identical to the PPE which is subject to the EC Type examination; under certificate number 03205494 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: 2005/12/12