

# EU DECLARATION OF CONFORMITY

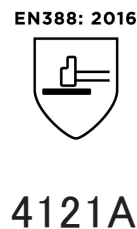
The Manufacturer  
**ANSELL HEALTHCARE EUROPE N.V.**  
RIVERSIDE BUSINESS PARK, BLOCK J  
BOULEVARD INTERNATIONAL 55  
B-1070 BRUSSELS  
BELGIUM  
WWW.ANSELL.COM

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

## AlphaTec® 58-005

*Products manufactured as of: [2025/07/29]*

PPE to be used against category III risks



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 21420:2020, EN ISO 374-1:2016, 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 032/2025/0474, 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: 2025/07/29

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BELGIUM  
**WWW.ANSELL.COM**

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

## AlphaTec® 58-005

*Products manufactured as of: [2022/09/09] and till: [2025/07/28]*

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

EN388: 2016



4122A

EN 407



X1XXXX

EN ISO 374-1:2016  
Type A



AJKLMNOP

T

EN ISO 374-5



VIRUS

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN407:2020, EN ISO 21420:2020, EN ISO 374-1:2016, 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 032/2021/1090, issued by the Notified Body:

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Guido Van Duren  
Director – Regulatory affairs  
Ansell

Place: Brussels  
Date: 2022/09/09

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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:

## AlphaTec® 58-005

*Products manufactured as of: [2021/10/27] and till: [2022/09/08]*

PPE to be used against category III risks

EN388: 2016



4122A

EN 407



X1XXXX

EN ISO 374-1:2016  
Type A



AJKLMNOP

T

EN ISO 374-5



VIRUS

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN407:2020, EN ISO 21420:2020, EN ISO 374-1:2016, 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 032/2021/1090, issued by the Notified Body:

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**BELGIUM**

Guido Van Duren  
Director – Regulatory affairs  
Ansell

Place: Brussels  
Date: 2021/10/27

# EU DECLARATION OF CONFORMITY

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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:

## AlphaTec® 58-005

*Products manufactured till: [2021/10/26]*

PPE to be used against category III risks



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016, EN 407:2004, EN 420:2003 + A1:2009, EN ISO 374-1:2016, 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 032/2020/1460, issued by the Notified Body:

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Guido Van Duren  
Director – Regulatory affairs  
Ansell

Place: Brussels  
Date: 2020/11/26