

# 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™ 38-003**

*Products manufactured as of: [2025/06/24]*

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

EN 16350



EN 421



EN ISO 374-1:2016  
Type A



**ABCIKM  
PST**

EN ISO 374-5



**VIRUS**

EN388: 2016



**1000X**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 16350:2014, EN 421:2010, EN ISO 21420:2020, 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 032/2025/0113.03, 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: 2025/06/24**

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

## AlphaTec® 38-003

*Products manufactured as of: [2025/03/17] and till: [2025/06/23]*

### PPE to be used against category III risks

EN 16350



EN 421



EN ISO 374-1:2016  
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**CENTEXBEL (0493)**  
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**BELGIUM**

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2025/03/17

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**ANSELL HEALTHCARE EUROPE N.V.**  
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**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
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**WWW.ANSELL.COM**

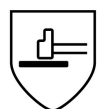
declares under his sole responsibility, that the PPE described hereafter:

**AlphaTec® 38-003**

*Products manufactured till: [2025/03/16]*

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

EN388: 2016



**1000X**

EN ISO 374-1:2016  
Type A



**ABCIKMP ST**

EN ISO 374-1:2016  
Type A



**ABCIKMP ST**

EN ISO 374-5:2016



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, 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 032/2024/0084, 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: 2024/02/05**