

# 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® 58-005**

*Products manufactured as of: [2022/09/09]*

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

EN388: 2016



4122A

EN 407



X1XXXX

EN ISO 374-1:2016  
Type A



AJKLMNOPT

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:

**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: 2022/09/09

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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:

## 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



AJKLMNOPT

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VIRUS

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TECHNOLOGIEPARK 70  
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BELGIUM



Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2021/10/27

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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:

**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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BELGIUM

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2020/11/26