

# 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> 04-002**

*Products manufactured as of: [2024/02/12]*

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

EN388: 2016



**3131A**

EN 407



**X1XXXX**

EN ISO 374-1:2016  
Type B



**JKL**

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, 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 032/2021/1109.02, 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: 2024/02/12

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**BELGIUM**

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

## AlphaTec® 04-002

*Products manufactured as of: [2021/10/29] and till: [2024/02/11]*

### PPE to be used against category III risks

EN388: 2016



**3131A**

EN 407



**X1XXXX**

EN ISO 374-1:2016  
Type B



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Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2021/10/29

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**BOULEVARD INTERNATIONAL 55**  
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**BELGIUM**

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

## AlphaTec® 04-002

*Products manufactured as of: [2020/09/30] and till: [2021/10/28]*

### PPE to be used against category III risks



3131A



JKL



X1XXXX

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016, EN ISO 374-1:2016 Type B, EN 420:2003 + A1:2009, EN ISO 374-5:2016, EN 407:2004 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/1530.02, issued by the Notified Body:

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Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2020/09/30

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**AlphaTec® 04-002**

*Products manufactured till: [2020/09/29]*

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

**EN 388**



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



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**BELGIUM**



Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2019/10/10