

# 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® 85-301**

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

EN ISO 374-1:2016  
Type B



**AMP**

EN388: 2016



**3101A**

EN ISO 374-5



**VIRUS**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016, EN 388:2016 +A1:2018, EN ISO 21420:2020, 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 032/2021/1308, 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: 2021/12/02**

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**Guido Van Duren**  
**Director - Regulatory affairs**  
**Ansell**

**Place: Brussels**  
**Date: 2023/12/20**

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

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*Products manufactured as of: [2021/01/12]*

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

EN ISO 374-5



**VIRUS**

EN ISO 374-1:2016  
Type B



**AMP**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-5:2016, EN ISO 374-1:2016 Type B and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/0665.03, issued by the Notified Body:

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**BELGIUM**

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**Guido Van Duren**  
**Director - Regulatory affairs**  
**Ansell**

**Place: Brussels**  
**Date: 2021/01/12**

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**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

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

**AlphaTec<sup>®</sup> 85-301**

*Products manufactured as of: [2020/11/16] and till: [2021/01/11]*

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

EN ISO 374-5



**VIRUS**

EN ISO 374-1:2016  
Type B



**AMP**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-5:2016, EN ISO 374-1:2016 Type B and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/0665.02, issued by the Notified Body:

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**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:

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**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

**Guido Van Duren**  
**Director - Regulatory affairs**  
**Ansell**

**Place: Brussels**  
**Date: 2020/02/16**

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**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
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**BELGIUM**

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

**AlphaTec® 85-301**

*Products manufactured as of: [2019/04/09] and till: [2020/11/15]*

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

EN ISO 374-5



**VIRUS**

EN ISO 374-1:2016  
Type B



**AMP**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-5:2016, EN ISO 374-1:2016 Type B and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/0665, issued by the Notified Body:

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**BELGIUM**

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

**Guido Van Duren**  
**Director - Regulatory affairs**  
**Ansell**

**Place: Brussels**  
**Date: 2019/04/09**

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**BELGIUM**

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

**AlphaTec<sup>®</sup> 85-301**

*Products manufactured till: [2019/04/08]*

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

**EN 374**



**AKL**

**EN 388**



**4101**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 374:2003, EN 388:2003 and is identical to the PPE which is subject to the EC Type examination; under certificate number IFA 1501064 issued by the Notified Body:

**INSTITUT FÜR ARBEITSSCHUTZ DER DGUV (IFA) (0121)**  
**PRÜF- UND ZERTIFIZIERUNGSSTELLE IM DGUV TEST**  
**ALTE HEERSTRASSE 111**  
**53754 SANKT AUGUSTIN**

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

**INSTITUT FÜR ARBEITSSCHUTZ DER DGUV (IFA) (0121)**  
**PRÜF- UND ZERTIFIZIERUNGSSTELLE IM DGUV TEST**  
**ALTE HEERSTRASSE 111**  
**53754 SANKT AUGUSTIN**

**Guido Van Duren**  
**Director - Regulatory affairs**  
**Ansell**

**Place: Brussels**  
**Date: 2015/10/20**