

# 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> 85-601**

*Products manufactured as of: [2021/12/09]*

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

EN388: 2016



**3100A**

EN ISO 374-1:2016  
Type B



**AMP**

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, 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 032/2021/1339, 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: 2021/12/09

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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<sup>®</sup> 85-601

*Products manufactured as of: [2020/11/12] and till: [2021/12/08]*

### PPE to be used against category III risks

EN ISO 374-1:2016  
Type B



**AMP**

EN ISO 374-5



**VIRUS**

EN 388



**3100A**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016 Type B, EN ISO 374-5:2016, EN 388:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/0667.02, 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: 2020/11/12

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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® 85-601**

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

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

EN ISO 374-1:2016  
Type B



**AMP**

EN ISO 374-5



**VIRUS**

EN 388



**3100A**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016 Type B, EN ISO 374-5:2016, EN 388:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/0667, 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: 2019/04/09

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**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> 85-601**

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

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

**EN 374**



**AKL**

**EN 388**



**3100**

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 1501066 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: 2015/08/30