

# 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> 85-501**

*Products manufactured as of: [2022.12.02]*

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

EN388: 2016



**2111A**

EN ISO 374-1:2016  
Type B



**KLP**

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 032/2021/1309, 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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**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> 85-501

*Products manufactured as of: [2020.07.15] and till: [2022.12.01]*

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



2111A

EN ISO 374-1:2016  
Type B



KLP

EN ISO 374-5



VIRUS

2016

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 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 032/2020/0978, 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: 2020.07.15

# 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® 85-501**

*Products manufactured till: [2020.07.14]*

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

EN 374



AKL

EN 388



4111

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 1501065 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: 2015.07.23