

# 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> 85-504**

*Products manufactured till: [2026/12/02]*

**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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RIVERSIDE BUSINESS PARK, BLOCK J  
BOULEVARD INTERNATIONAL 55  
B-1070 BRUSSELS  
BELGIUM

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

**AlphaTec® 85-504**

*Products manufactured as of: [2020/07/15]*

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



**2111A**



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, EN 420:2003 + A1:2009 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  
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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  
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Guido Van Duren  
Director - Regulatory affairs  
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Place: Brussels  
Date: 2020/07/15

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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® 85-504**

*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, EN 420:2003 + A1:2009 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