

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® 85-303

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

PPE to be used against category III risks

EN ISO 374-1:2016
Type B



AMP

EN ISO 374-5



VIRUS

EN 388



3101A

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016, EN ISO 374-5:2016, EN 388:2016, 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 032/2019/0665.03, 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: 2021/01/12

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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[®] 85-303

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

PPE to be used against category III risks

EN ISO 374-1:2016
Type B



AMP

EN ISO 374-5



VIRUS

EN 388



3101A

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016, EN ISO 374-5:2016, EN 388:2016, 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 032/2019/0665.02, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
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BELGIUM

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BELGIUM

Guido Van Duren
Director - Regulatory affairs
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Place: Brussels
Date: 2020/11/16

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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® 85-303

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

PPE to be used against category III risks

EN ISO 374-1:2016
Type B



AMP

EN ISO 374-5



VIRUS

EN 388



3101A

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016, EN ISO 374-5:2016, EN 388:2016, 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 032/2019/0665, 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

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[®] 85-303

Products manufactured till: [2019/04/08]

PPE to be used against category III risks

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 420:2003 + A1:2009 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