

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® 85-304

Products manufactured as of: [2023/12/20]

PPE to be used against category III risks

EN388: 2016



3101A

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 032/2021/1308.02, 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: 2023/12/20

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[®] 85-304

Products manufactured as of: [2021/12/02] and till: [2023/12/19]

PPE to be used against category III risks

EN388: 2016



3101A

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 032/2021/1308, issued by the Notified Body:

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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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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[®] 85-304

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

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:

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

A handwritten signature in black ink, appearing to read 'Guido Van Duren', written over a horizontal line.

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2021/01/12

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[®] 85-304

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:

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

A handwritten signature in black ink, appearing to read 'Guido Van Duren', written over a horizontal line.

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2020/11/16

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[®] 85-304

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:

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

A handwritten signature in black ink, appearing to read 'Guido Van Duren', written over a horizontal line.

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[®] 85-304

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