

EU DECLARATION OF CONFORMITY

The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM

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

AlphaTec® 04-002

Products manufactured as of: [2025/01/31]

PPE to be used against category III risks

EN388: 2016



3131A

EN 407



X1XXXX

EN ISO 374-1:2016
Type B



JKL

EN ISO 374-5:2016



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN407:2020 , 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 032/2021/1109.03, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VIII (Module D) 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: 2025/01/31

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BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM

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

AlphaTec® 04-002

Products manufactured as of: [2024/02/12] and till: [2025/01/30]

PPE to be used against category III risks

EN388: 2016



3131A

EN 407



X1XXXX

EN ISO 374-1:2016
Type B



JKL

EN ISO 374-5:2016



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN407:2020 , 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 032/2021/1109.02, 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: 2024/02/12

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ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
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declares under his sole responsibility, that the PPE described hereafter:

AlphaTec® 04-002

Products manufactured as of: [2021/10/29] and till: [2024/02/11]

PPE to be used against category III risks

EN388: 2016



3131A

EN 407



X1XXXX

EN ISO 374-1:2016
Type B



JKL

EN ISO 374-5:2016



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN407:2020, 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 032/2021/1109, issued by the Notified Body:

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CENTEXBEL (0493)
TECHNOLOGIEPARK 70
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BELGIUM



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2021/10/29

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BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM

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

AlphaTec® 04-002

Products manufactured as of: [2020/09/30] and till: [2021/10/28]

PPE to be used against category III risks



3131A



X1XXXX

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 420:2003 + A1:2009, EN ISO 374-5:2016, EN 407:2004 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/1530.02, issued by the Notified Body:

CENTEXBEL (0493)
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CENTEXBEL (0493)
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B-9052 ZWIJNAARDE
BELGIUM



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2020/09/30

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EN ISO 374-5:2016



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X1XXXX

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 420:2003 + A1:2009, EN ISO 374-5:2016, EN 407:2004 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/1530, issued by the Notified Body:

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BELGIUM**

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2019/10/10