

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™ 38-001

Products manufactured as of: [2026/08/21]

PPE to be used against category III risks

EN 16350



EN 421



EN ISO 374-1:2016
Type A



ABCIKMP
ST

EN ISO 374-5



VIRUS

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 16350:2014, EN 421:2010, EN ISO 21420:2020+A1:2024, EN ISO 374-1:2016+A1:2018, 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 032/2026/0454, 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: 2026/08/21

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

AlphaTec® 38-001

Products manufactured as of: [2025/02/21] and till: [2026/08/20]

PPE to be used against category III risks

EN 16350



EN 421



**EN ISO 374-1:2016
Type A**



**ABCIKMP
ST**

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BELGIUM**

Guido Van Duren
Director - Regulatory affairs
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Place: Brussels
Date: 2025/02/21

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B-1070 BRUSSELS
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declares under his sole responsibility, that the PPE described hereafter:

AlphaTec® 38-001

Products manufactured as of: [2024/06/24] and till: [2025/02/20]

PPE to be used against category III risks

EN 421



EN ISO 374-5



VIRUS

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 421:2010, 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 032/2024/0361, issued by the Notified Body:

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BELGIUM

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2024/06/24

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AlphaTec® 38-001

Products manufactured till: [2024/06/23]

PPE to be used against category III risks

EN ISO 374-5:2016



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 21420:2020, 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 032/2023/0694, 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: 2023/07/27