

UK 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

UK Importer
PATIENT GUARD LTD
LANCASTER HOUSE,
AMY JOHNSON WAY,
BLACKPOOL, LANCASHIRE,
FY4 2RP, UNITED KINGDOM
INFO@PATIENTGUARD.CO.UK

declare under their sole responsibility, that the PPE described hereafter:

AlphaTec™ 38-003

Products manufactured as of: [2025/06/24]

PPE to be used against category III risks

EN 16350



EN 421



EN ISO 374-1:2016
Type A



EN ISO 374-5



ABCIKMPST

VIRUS

EN388: 2016



1000X

is in conformity with the provisions of Regulation 2016/425 on personal protective equipment, as amended to apply in GB, and with the standards EN 16350:2014, EN 421:2010, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 388:2016 +A1:2018 and is identical to the PPE which is subject to the Type-examination (Module B, Annex V of the Regulation), under certificate number 032/2025/0113.03, issued by the Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the conformity assessment procedure set in out in Annex VIII (Module D) of the Regulation under the surveillance of the Approved Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2025/06/24

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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® 38-003

Products manufactured as of: [2025/03/17] and till: [2025/06/23]

PPE to be used against category III risks

EN 16350



EN 421



EN ISO 374-1:2016
Type A



EN ISO 374-5



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VIRUS

EN388: 2016



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TECHNOLOGIEPARK 70
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and is subject to the conformity assessment procedure set in out in Annex VIII (Module D) of the Regulation under the surveillance of the Approved Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2025/03/17

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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® 38-003

Applicable Until [2025/03/16]

PPE to be used against category III risks

EN388: 2016



EN ISO 374-1:2016
Type A



EN ISO 374-1:2016
Type A



EN ISO 374-5:2016



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is in conformity with the provisions of Regulation 2016/425 on personal protective equipment, as amended to apply in GB, 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 UK Type-examination (Module B, Annex V of the Regulation), under certificate number AB0321/25675-01/E00-00, issued by the Approved Body:

**SATRA TECHNOLOGY CENTRE (0321)
WYNDHAM WAY, TELFORD WAY,
KETTERING, NORTHAMPTONSHIRE,
NN16 8SD, UNITED KINGDOM**

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

**SATRA TECHNOLOGY CENTRE (0321)
WYNDHAM WAY, TELFORD WAY,
KETTERING, NORTHAMPTONSHIRE,
NN16 8SD, UNITED KINGDOM**

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2024/05/09