

# 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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**B-1070 BRUSSELS**  
**BELGIUM**  
**WWW.ANSELL.COM**

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

## **AlphaTec® 38-003**

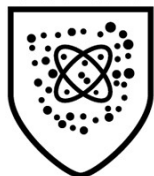
*Products manufactured as of: [2025/03/17] and till: [2025/06/23]*

**PPE to be used against category III risks**

EN 16350



EN 421



EN ISO 374-1:2016  
Type A



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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:

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**TECHNOLOGIEPARK 70**  
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**BELGIUM**

**Guido Van Duren**  
**Director - Regulatory affairs**  
**Ansell**

**Place: Brussels**  
**Date: 2025/03/17**

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**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



**ABCIKMPSÆBCIKMPST**

**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 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**