

# 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



ABCIKMPST

EN ISO 374-5



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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BELGIUM  
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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**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

A handwritten signature in black ink, appearing to read 'Guido Van Duren'.

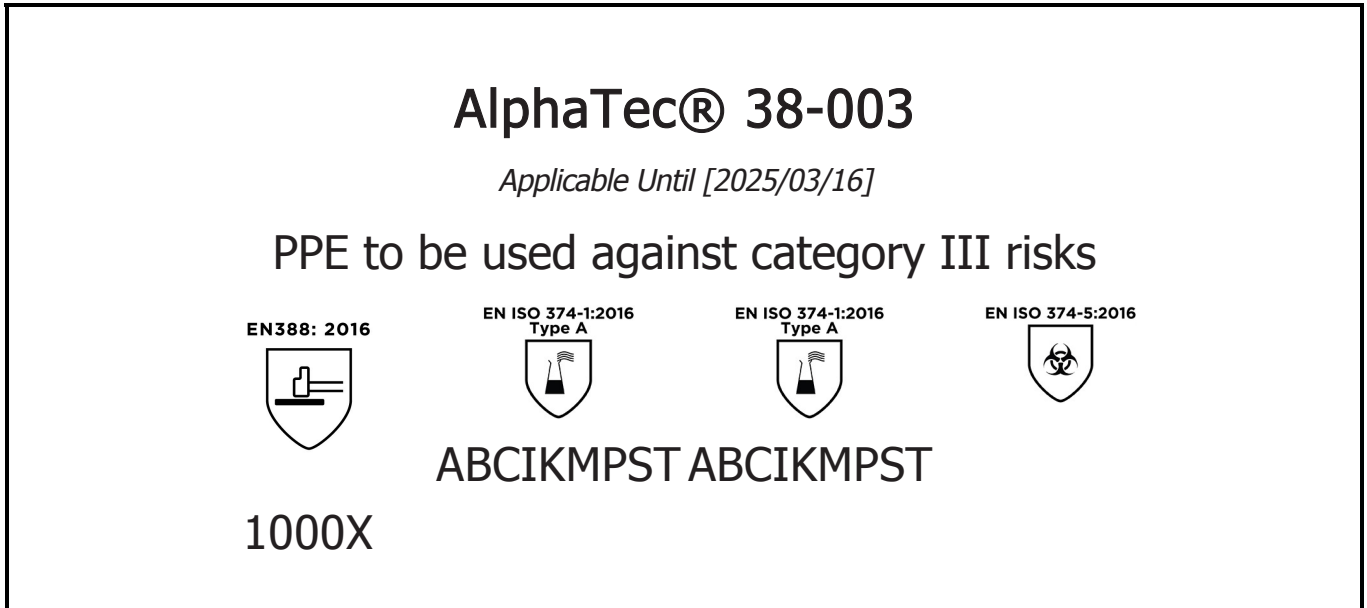
Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2025/03/17

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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