

# 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® 58-008

*Products manufactured as of: [2025/01/30]*

PPE to be used against category III risks

EN388: 2016



EN ISO 374-1:2016  
Type A



EN ISO 374-5:2016



AJKLOT

4102X

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 032/2021/1266.02, issued by the Approved 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: 2025/01/30

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RIVERSIDE BUSINESS PARK, BLOCK J  
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BELGIUM  
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declares under his sole responsibility, that the PPE described hereafter:

**AlphaTec® 58-008**

*Applicable Until [2025/01/29]*

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

EN388: 2016



EN ISO 374-1:2016  
Type A



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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 AB0321/24091-01/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 conformity assessment procedure set out in Annex VII (Module C2) of the Regulation under the surveillance of the Approved 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: 2023/04/24