

# 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® 53-003**

*Products manufactured as of: [2025/05/05]*

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

EN388: 2016



**2121X**

EN 407



**X1XXXX**

EN 421



EN ISO 374-1:2016  
Type A



**ABCEFGHIJKLMNOPST**

EN ISO 374-5



**VIRUS**

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, EN407:2020 , EN 421:2010, EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016 and is identical to the PPE which is subject to the Type-examination (Module B, Annex V of the Regulation), under certificate number 032/2024/0136.02, 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: 2025/05/05

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**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**  
**WWW.ANSELL.COM**

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

**AlphaTec® 53-003**

*Applicable Until [2025/05/04]*

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



2121X



X1XXXX



ABCEFGHIJKLMNOPST

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 421:2010, EN ISO 374-5:2016, EN 388:2016 +A1:2018, EN407:2020 , EN ISO 374-1:2016 and is identical to the PPE which is subject to the Type-examination (Module B, Annex V of the Regulation), under certificate number 032/2024/0136, issued by the 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: 2024/02/27