

# 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® 37-300

*Products manufactured as of: [2024/11/08]*

### PPE to be used against category III risks

EN388: 2016



2001X

EN 421



EN ISO 374-1:2016  
Type B



JKT

EN ISO 374-5



VIRUS



ISO 18889  
G1

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 421:2010, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016, ISO 18889:2019 and is identical to the PPE which is subject to the Type-examination (Module B, Annex V of the Regulation), under certificate number 032/2024/0589, 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: 2024/11/08

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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® 37-300**

*Applicable Until [2024/11/07]*

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

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

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:

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



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

**Place: Brussels**  
**Date: 2022/07/21**