

# 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® 02-100

*Products manufactured as of: [2025/01/27]*

PPE to be used against category III risks

EN ISO 374-1:2016  
Type A



EN ISO 374-5



ABCDEFGHIILMS

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 ISO 374-1:2016, 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 032/2021/1447.04, 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**

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

Guido Van Duren  
Director – Regulatory affairs  
Ansell

Place: Brussels  
Date: 2025/01/27

# UK DECLARATION OF CONFORMITY

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**ANSELL HEALTHCARE EUROPE N.V.**  
**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® 02-100

*Products manufactured as of: [2024/09/04] and till: [2025/01/26]*

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

EN ISO 374-1:2016  
Type A



**ABCEFGHILMS**

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 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 AB0321/23415-02/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**

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Guido Van Duren  
Director – Regulatory affairs  
Ansell

Place: Brussels  
Date: 2024/09/04

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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® 02-100**

*Applicable Until [2024/09/03]*

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

EN ISO 374-1:2016  
Type A



**ABCEFGHILMS**

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 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 AB0321/23415-01/E00-00, issued by the Approved Body:

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

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KETTERING, NORTHAMPTONSHIRE,  
NN16 8SD, UNITED KINGDOM**

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Guido Van Duren  
Director – Regulatory affairs  
Ansell

Place: Brussels  
Date: 2023/01/17