

# UK DECLARATION OF CONFORMITY

The Manufacturer  
**ANSELL HEALTHCARE EUROPE N.V.**  
**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

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

**AlphaTec® 85-300**

*Products manufactured as of: [2025/02/07]*

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

EN388: 2016



**3101A**

EN ISO 374-1:2016  
Type B



**AMP**

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, 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 Type-examination (Module B, Annex V of the Regulation), under certificate number 032/2021/1308.03, 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: 2025/02/07

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**ANSELL HEALTHCARE EUROPE N.V.**  
**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

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

## AlphaTec<sup>®</sup> 85-300

*Products manufactured as of: [2023/12/20] and till: [2025/02/06]*

### PPE to be used against category III risks

EN388: 2016



3101A

EN ISO 374-1:2016  
Type B



AMP

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, 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 032/2021/1308.02/UKCA, issued by the Approved Body:

**CENTEXBEL INTERNATIONAL LTD,  
8 NORTHUMBERLAND AVENUE,  
LONDON, WC2N 5BY,  
UK**

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:

**CENTEXBEL INTERNATIONAL LTD,  
8 NORTHUMBERLAND AVENUE,  
LONDON, WC2N 5BY,  
UK**

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2023/12/20

# UK DECLARATION OF CONFORMITY

The Manufacturer  
**ANSELL HEALTHCARE EUROPE N.V.**  
**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

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

**AlphaTec® 85-300**

*Applicable Until [2023/12/19]*

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

EN388: 2016



**3101A**

EN ISO 374-1:2016  
Type B



**AMP**

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, 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 AB0321/23004-01/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: 2022/11/30