

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® 85-305

Products manufactured as of: [2023/12/20]

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

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ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
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declares under his sole responsibility, that the PPE described hereafter:

AlphaTec[®] 85-305

Applicable Until [2023/12/19]

PPE to be used against category III risks

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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 AB0321/23004-01/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