

UK DECLARATION OF CONFORMITY

The Manufacturer
ANSELL HEALTHCARE EUROPE NV

**REGISTERED OFFICE UNTIL 31
DECEMBER 2026:
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS, BELGIUM**

**REGISTERED OFFICE FROM 1
JANUARY 2027:
KOUTERVELDSTRAAT 2
1831 DIEGEM (MACHELEN), BELGIUM**

**THE LEGAL ENTITY AND SCOPE OF
CERTIFICATION REMAIN
UNCHANGED. THE REGISTERED
OFFICE ADDRESS WILL CHANGE
WITH EFFECT FROM 1 JANUARY
2027.
DURING THE TRANSITION PERIOD,
PRODUCTS MAY BEAR EITHER THE
PREVIOUS OR THE NEW REGISTERED
OFFICE ADDRESS.**

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™ 53-001

Products manufactured as of: [2026/10/16]

PPE to be used against category III risks

EN388: 2016



3121A

EN 407



X1XXXX

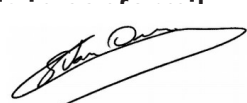
EN ISO 374-1:2016
Type A



EN ISO 374-5:2016



ACFGJKLMNOPST


with the provisions of Regulation 2016/425 on personal protective
ended to apply in GB, and with the standards EN 388:2016 +A1:2018,
ISO 21420:2020+A1:2024, 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 032/2026/0551, issued by the Body:
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2026/10/16

**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)

BELGIUM

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

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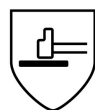
declare under their sole responsibility, that the PPE described hereafter:

AlphaTec® 53-001

Applicable Until [2026/10/15]

PPE to be used against category III risks

EN388: 2016



3121A

EN 407



X1XXXX

EN ISO 374-1:2016
Type A



EN ISO 374-5:2016



ACFGJKLMNOPST

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 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 AB0321/22020-01/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 in out in Annex VIII (Module D) of the Regulation under the surveillance of the Approved Body:

Guido Van Duren
Director - Regulatory affairs
Ansell

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

Place: Brussels
Date: 2022/07/28

