

EU 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.**

declares under his 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

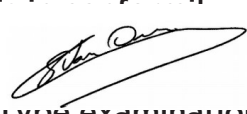
EN ISO 374-1:2016
Type A



**ACFGJKL
MNOPST**

EN ISO 374-5:2016




with the provisions of Regulation (EU) 2016/425 and with the standards EN
3, EN407:2020 , EN ISO 21420:2020+A1:2024, EN ISO 374-
N ISO 374-5:2016 and is identical to the PPE which is subject to the EU-
type examination (Module B, Annex V of the Regulation), under certificate number
032/2026/DEN issued by the Notified Body:
Director - Regulatory affairs
Ansell
Place: Brussels
Date: 2026/10/16

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VIII (Module D) of the Regulation under the supervision of the Notified 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

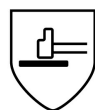
declares under his sole responsibility, that the PPE described hereafter:

AlphaTec® 53-001

Products manufactured as of: [2021/10/18] and till: [2026/10/15]

PPE to be used against category III risks

EN388: 2016



3121A

EN 407



X1XXXX

EN ISO 374-1:2016
Type A



**ACFGJKL
MNOPST**

EN ISO 374-5:2016



is in conformity with the provisions of Regulation (EU) 2016/425 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 EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2021/1047, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VIII (Module D) of the Regulation under the supervision of the Notified Body:



CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2021/10/18

EU 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

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

AlphaTec® 53-001

Products manufactured till: [2021/10/17]

PPE to be used against category III risks

EN 388



3121A

**EN ISO 374-1:2016
Type A**



**ACFGJKL
MNOPST**

EN ISO 374-5:2016



EN 407



X1XXXX

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 407:2004, EN 420:2003 + A1:2009 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/1065, issued by the Notified Body:

**CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM**

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

**CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM**



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2019/06/11

