

EU 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® 19-024

Products manufactured as of: [2021/10/27]

PPE to be used against category III risks

EN388: 2016



3122B

EN 511



121

EN ISO 374-1:2016
Type A



AKLMPT

EN ISO 374-5:2016



EN 407



32XX4X

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN 511:2006, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016, EN407:2020 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2021/1091, 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: 2021/10/27

EU DECLARATION OF CONFORMITY

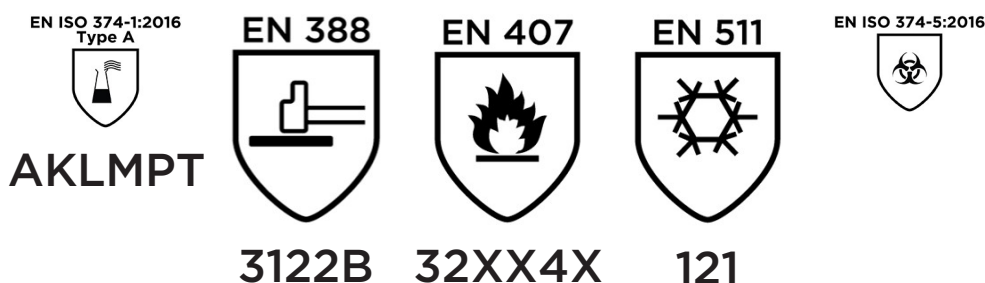
The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM

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

Alphatec[®] 19-024

Products manufactured as of: [2020/01/01] and till: [2021/10/26]

PPE to be used against category III risks



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016, EN 388:2016, EN 407:2004, EN 420:2003 + A1:2009, EN 511:2006, 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 032/2018/2167, 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: 2020/01/01

EU DECLARATION OF CONFORMITY

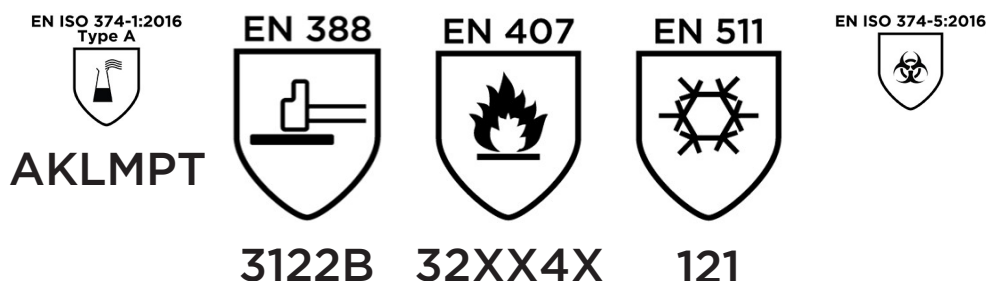
The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM

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

Alphatec[®] 19-024

Products manufactured as of: [2018/12/19] and till: [2019/12/31]

PPE to be used against category III risks



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016, EN 388:2016, EN 407:2004, EN 420:2003 + A1:2009, EN 511:2006, 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 032/2018/2167, 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:

BSI (0086)
KITEMARK COURT DAVY AVENUE KNOWLHILL
MILTON KEYNES MK5 8PP UNITED KINGDOM

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2018/12/19

EU DECLARATION OF CONFORMITY

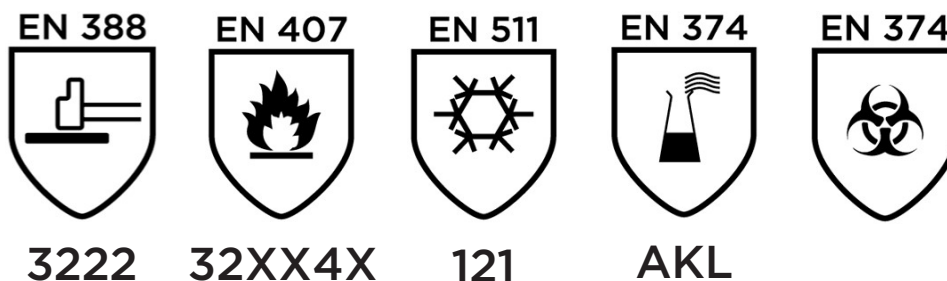
The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM

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

Scorpio 19-024

Products manufactured till: [2018/12/18]

PPE to be used against category III risks



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2003, EN 407:2004, EN 420:2003 + A1:2009, EN 511:2006, EN 374:2003, and is identical to the PPE which is subject to the EC Type examination; under certificate number 03213527 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: 2013/07/12