

# EU DECLARATION OF CONFORMITY

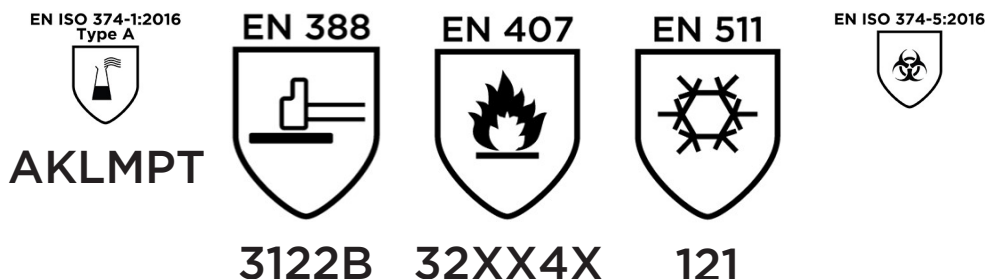
The Manufacturer  
**ANSELL HEALTHCARE EUROPE N.V.**  
**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

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

**Alphatec® 19-024**

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

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



is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized 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: 19/12/2018**

# EU DECLARATION OF CONFORMITY

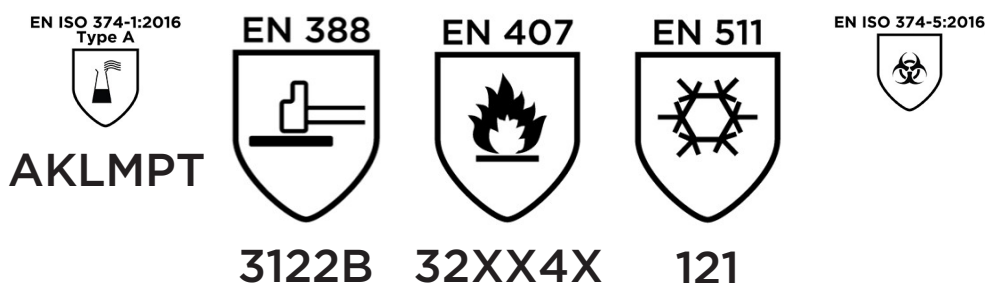
The Manufacturer  
**ANSELL HEALTHCARE EUROPE N.V.**  
**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

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

## Alphatec<sup>®</sup> 19-024

*Products manufactured as of: [01/01/2020]*

### PPE to be used against category III risks



is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized 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: 01/01/2020**

# EU DECLARATION OF CONFORMITY

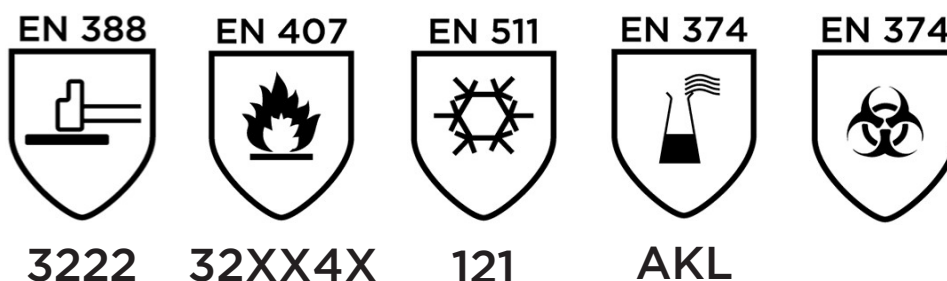
The Manufacturer  
**ANSELL HEALTHCARE EUROPE N.V.**  
**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

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

## Scorpio 19-024

*Products manufactured till: [18/12/2018]*

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



is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized 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: 12/07/2013**