

# 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® 37-340

*Products manufactured as of: [01/08/2019]*

### PPE to be used against category III risks



3121A



X1XXXX



JKLOPT



is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized standards EN 388:2016, EN 407:2004, EN 420:2003 + A1:2009, 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 032/2019/0863, 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: 01/08/2019

# 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® 37-340

*Products manufactured as of: [25/07/2019] and till: [31/07/2019]*

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

EN 388



3121A

EN 407



X1XXXX

EN ISO 374-1:2016  
Type A



JKLOPT

EN ISO 374-5:2016



is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized standards EN 388:2016, EN 407:2004, EN 420:2003 + A1:2009, 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 032/2019/0863, 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 GROUP THE NETHERLANDS B.V. (2797)**  
**SAY BUILDING, JOHN M. KEYNESPLEIN 9, 1066 EP**  
**AMSTERDAM**  
**NETHERLANDS**



Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 25/07/2019

# 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:

## AlpaTec® 37-340

*Products manufactured as of: [08/05/2019] and till: [24/07/2019]*

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

EN 388



3121A

EN 407



X1XXXX

EN ISO 374-1:2016  
Type A



JKLOPT

EN ISO 374-5:2016



is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized standards EN 388:2016, EN 407:2004, EN 420:2003 + A1:2009, 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 032/2019/0863, 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: 08/05/2019

# EU DECLARATION OF CONFORMITY

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

and authorized representative:  
**COMASEC S.A.S**  
5 ALLÉE DES BAS TILLIERS  
92238 GENNEVILLIERS CEDEX  
FRANCE

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

## Comfort G26G

*Products manufactured till: [07/05/2019]*

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

EN 374



AJKL

EN 374



EN 388



3121

EN 407



X1XXXX

is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized standards EN 374:2003, EN 388:2003, EN 407:2004, EN 420:2003 + A1:2009 and is identical to the PPE which is subject to the EC Type examination; under certificate number 561433 issued by the Notified Body:

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

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: 26/05/2010