

# 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> Solvex<sup>®</sup> 37-675**

*Products manufactured as of: [2024/02/13]*

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

EN388: 2016



**4101X**

EN ISO 374-1:2016  
Type A



**JKLOPT**

EN ISO 374-5



**VIRUS**



**ISO 18889**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016, ISO 18889:2019 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2021/1068.03, 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: 2024/02/13**

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

**AlphaTec<sup>®</sup> Solvex<sup>®</sup> 37-675**

*Products manufactured as of: [2023/08/02] and till: [2024/02/12]*

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

EN388: 2016



**4101X**

EN ISO 374-1:2016  
Type A



**JKLOPT**

EN ISO 374-5



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**ISO 18889**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016, ISO 18889:2019 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2021/1068.02, issued by the Notified Body:

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Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2023/08/02

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**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

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

## AlphaTec® Solvex® 37-675

*Products manufactured as of: [2021/10/21] and till: [2023/08/01]*

### PPE to be used against category III risks

EN388: 2016



4101X

EN ISO 374-1:2016  
Type A



JKLOPT

EN ISO 374-5



VIRUS



ISO 18889  
G2

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016, ISO 18889:2019 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2021/1068, issued by the Notified Body:

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

A handwritten signature in black ink, appearing to read 'Guido Van Duren'.

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2021/10/21

# 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® Solvex® 37-675

*Products manufactured as of: [2019/10/07] and till: [2021/10/20]*

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

EN ISO 374-1:2016  
Type A



**JKLOPT**

EN 388



**4101X**



EN ISO 374-5:2016



**VIRUS**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016, EN 388:2016, EN 420:2003 + A1:2009, ISO 18889:2019, 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 032/2019/1519, 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**

A handwritten signature in black ink, appearing to read 'Guido Van Duren'.

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2019/10/07

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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:

**Solvex<sup>®</sup> 37-675**

*Products manufactured till: [2019/10/06]*

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



4101



JKL



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2003, EN 420:2003 + A1:2009, EN 374:2003, and is identical to the PPE which is subject to the EC Type examination; under certificate number 03205085 issued by the Notified Body:

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



Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2005/03/21