

# 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> 87-320**

*Products manufactured as of: [2024/10/04]*

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

EN ISO 374-1:2016  
Type B



**KLT**

EN ISO 374-5:2016



EN388: 2016



**1010X**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016, EN ISO 374-5:2016, EN 388:2016 +A1:2018 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2024/0535, 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**

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

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2024/10/04

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The Manufacturer  
**ANSELL HEALTHCARE EUROPE N.V.**  
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**BELGIUM**

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

**AlphaTec<sup>®</sup> 87-320**

*Products manufactured as of: [2022/03/04] and till: [2024/10/03]*

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

EN388: 2016



**1010X**

EN ISO 374-1:2016  
Type B



**KLT**

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, 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 032/2022/0331, issued by the Notified Body:

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**TECHNOLOGIEPARK 70**  
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**BELGIUM**



Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2022/03/04

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**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
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**BELGIUM**

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

**AlphaTec® 87-320**

*Products manufactured as of: [2021/04/09] and till: [2022/03/03]*

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

EN ISO 374-1:2016  
Type B



**KLT**

EN ISO 374-5:2016



EN 388



**2010X**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016 Type B, EN ISO 374-5:2016, EN 388:2016, 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 032/2019/0079.03, issued by the Notified Body:

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**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

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**B-9052 ZWIJNAARDE**  
**BELGIUM**

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Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2021/04/09

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**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> 87-320**

*Products manufactured as of: [2021/01/11] and till: [2021/04/08]*

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

EN ISO 374-1:2016  
Type B



**KLT**

EN ISO 374-5:2016



EN 388



**2010X**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016 Type B, EN ISO 374-5:2016, EN 388:2016, 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 032/219/0079.02, 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**

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

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2021/01/11

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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<sup>®</sup> 87-320**

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

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

EN ISO 374-1:2016  
Type B



**KLT**

EN ISO 374-5:2016



EN 388



**2010X**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016 Type B, EN ISO 374-5:2016, EN 388:2016, 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 032/2019/0079, 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

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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® 87-320**

*Products manufactured till: [2019/12/31]*

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

EN ISO 374-1:2016  
Type B



**KLT**

EN ISO 374-5:2016



EN 388



**2010X**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016 Type B, EN ISO 374-5:2016, EN 388:2016, 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 032/2019/0079, issued by the Notified Body:

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**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**

A handwritten signature in black ink.

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2019/01/17