

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: [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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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: [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



VIRUS



G2
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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B-9052 ZWIJNAARDE
BELGIUM

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2023/08/02

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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® 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

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:

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: 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

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CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

A handwritten signature in black ink.

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2019/10/07

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:

Solvex[®] 37-675

Products manufactured till: [2019/10/06]

PPE to be used against category III risks

EN 388



4101

EN 374



JKL

EN 374



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)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
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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)
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B-9052 ZWIJNAARDE
BELGIUM

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2005/03/21