

EU DECLARATION OF CONFORMITY

The Manufacturer
**ANSELL HEALTHCARE EUROPE
NV/SA
KOUTERVELDSTRAAT 2
1831 DIEGEM (MACHELEN)
BELGIUM**

and authorized representative:
**PATIENT GUARD LTD
LANCASTER HOUSE,
AMY JOHNSON WAY,
BLACKPOOL, LANCASHIRE,
FY4 2RP, UNITED KINGDOM
INFO@PATIENTGUARD.CO.UK**

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

AlphaTec™ 37-676

Products manufactured as of: [2026/10/01]

PPE to be used against category III risks

EN388: 2016



4101X

EN ISO 374-1:2016
Type A



JKLNOPT

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 374-1:2016+A1:2018, 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 032/2026/0513, issued by the Notified Body:

and is subject to the procedure set out in Annex VIII (Module D) of the Regulation under the supervision of the Notified Body:



**Guido Van Duren
Director - Regulatory affairs
Ansell**

**Place: Brussels
Date: 2026/10/01**

EU DECLARATION OF CONFORMITY

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

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

AlphaTec® Solvex® 37-676

Products manufactured as of: [2021/10/22] and till: [2026/09/30]

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 032/2021/1070, 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:



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2021/10/22

EU DECLARATION OF CONFORMITY

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

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

AlphaTec® Solvex® 37-676

Products manufactured as of: [2020/01/06] and till: [2021/10/21]

PPE to be used against category III risks



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, 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 032/2020/0005, 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: 2020/01/06

EU DECLARATION OF CONFORMITY

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

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

Solvex® 37-676

Products manufactured till: [2020/01/05]

PPE to be used against category III risks

EN 374



JKL

EN 388



4101

EN 374



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 374:2003, EN 388:2003, EN 420:2003 + A1:2009, and is identical to the PPE which is subject to the EC Type examination; under certificate number 03205088 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: 2005/03/21