

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: [07/10/2019]

PPE to be used against category III risks

EN ISO 374-1:2016
Type A



JKLOPT

EN 388



4101X



ISO 18889
G2

EN ISO 374-5:2016



VIRUS

is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized 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

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 07/10/2019

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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:

Solvex[®] 37-675

Products manufactured till: [06/10/2019]

PPE to be used against category III risks



4101

is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized standards 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 03205085 issued by the Notified Body:

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BELGIUM

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 21/03/2005