

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[®] 38-514

Products manufactured as of: [2025/01/31]

PPE to be used against category III risks

EN388: 2016



1000X

EN ISO 374-1:2016
Type A



ABCIKMPST

EN ISO 374-5



VIRUS

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 032/2021/1154.03, 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: 2025/01/31

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[®] 38-514

Products manufactured as of: [2024/02/27] and till: [2025/01/30]

PPE to be used against category III risks

EN388: 2016



1000X

EN ISO 374-1:2016
Type A



ABCIKMPST

EN ISO 374-5



VIRUS

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 032/2021/1154.02, 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: 2024/02/27

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[®] 38-514

Products manufactured as of: [2018/05/28] and till: [2024/02/26]

PPE to be used against category III risks

EN ISO 374-1:2016
Type A



EN ISO 374-5:2016



ABCIKMPST

EN 388



1000X

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 032/2018/0877, 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: 2018/05/28

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:

ChemTek™ 38-514

Products manufactured till: [2018/05/27]

PPE to be used against category III risks



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 03210115 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: 2010/03/15