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® 55-101

Products manufactured as of: [2022/03/11]

PPE to be used against category III risks

EN388: 2016



2121A

EN ISO 374-1:2016
Type A



KLNOPT

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 032/2022/0338, 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: 2022/03/11

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® 55-101

Products manufactured as of: [2019/07/31] and till: [2022/03/10]

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 032/2019/0841, 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: 2019/07/31

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® 55-101

Products manufactured as of: [2019/05/07] and till: [2019/07/30]

PPE to be used against category III risks

EN ISO 374-1:2016 Type A



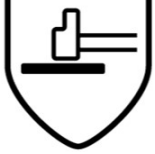
KLNOPT

EN ISO 374-5



VIRUS

EN 388



2121A

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 032/2019/0841, 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:

BSI (0086)
KITEMARK COURT DAVY AVENUE KNOWLHILL
MILTON KEYNES MK5 8PP UNITED KINGDOM



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2019/05/07

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:

AlphaTec® 55-101

Products manufactured till: [2019/05/06]

PPE to be used against category III risks



3121

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 03213890 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:

BSI (0086)
KITEMARK COURT DAVY AVENUE KNOWLHILL
MILTON KEYNES MK5 8PP UNITED KINGDOM



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2013/12/12