

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® 58-001

Products manufactured as of: [2022/02/18]

PPE to be used against category III risks

EN388: 2016



4101X

EN ISO 374-1:2016
Type A



AJKLOPT

EN ISO 374-5



VIRUS

EN 16350



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, EN 16350:2014 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2022/0239, 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: 2022/02/18

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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® 58-001

Products manufactured till: [2022/02/17]

PPE to be used against category III risks

EN ISO 374-5



VIRUS

EN 1149



EN 16350



EN 388



EN ISO 374-1:2016
Type A



AJKLOPT

4101X

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 420:2003 + A1:2009, EN ISO 374-5:2016, EN 1149, EN 16350:2014, EN 388:2016, EN ISO 374-1:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2021/0011, issued by the Notified Body:

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Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2021/01/08