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:



Products manufactured as of: [2025/01/09]

PPE to be used against category III risks













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is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN407:2020, EN 511:2006, 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 032/2021/1446.03, 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: 2025/01/09

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® 62-401

Products manufactured as of: [2023/08/02] and till: [2025/01/08]

PPE to be used against category III risks











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is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN407:2020, EN 511:2006, 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 032/2021/1446.02, 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: 2023/08/02

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® 62-401

Products manufactured as of: [2021/12/24] and till: [2023/08/01]

PPE to be used against category III risks











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is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN407:2020, EN 511:2006, 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

CENTEXBEL (0493) TECHNOLOGIEPARK 70 B-9052 ZWIJNAARDE BELGIUM

Regulation), under certificate number 032/2021/1446, issued by the Notified Body:

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: 2021/12/24

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:



Products manufactured as of: [2020/08/14] and till: [2021/12/23]

PPE to be used against category III risks











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is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016, EN 388:2016, EN 407:2004, EN 420:2003 + A1:2009, EN 511:2006, 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 032/2020/1086, 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: 2020/08/14

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:



Products manufactured as of: [2019/04/01] and till: [2020/08/13]

PPE to be used against category III risks











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is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016, EN 388:2016, EN 407:2004, EN 420:2003 + A1:2009, EN 511:2006, 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 032/2019/0549, 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: 2019/04/01

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:

### VersaTouch 62-401

Products manufactured till: [2019/03/31]

PPE to be used against category III risks



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is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 374:2003, EN 388:2003, EN 407:2004, EN 420:2003 + A1:2009, EN 511:2006, and is identical to the PPE which is subject to the EC Type examination; under certificate number 03214026 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: 2014/01/30