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:

# GAMMEX® Latex Ortho

Products manufactured as of: [2022/02/22]

PPE to be used against category III risks

EN388: 2016



EN ISO 374-1:2016 Type B



0010X

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 032/2022/0253, 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: 2022/02/22

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:

# GAMMEX® Latex Ortho

Products manufactured as of: [2020/05/15] and till: [2022/02/21]

PPE to be used against category III risks

EN ISO 374-1:2016 Type B



EN ISO 374-5

**VIRUS** 

0010X

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016, EN 420:2003 + A1:2009, EN ISO 374-1:2016 Type B, 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 032/2019/0833, 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: 2020/05/15

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:

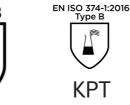
# GAMMEX® Latex Ortho

Products manufactured as of: [2019/07/25] and till: [2020/05/14]

PPE to be used against category III risks



0010X





is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016, EN 420:2003 + A1:2009, EN ISO 374-1:2016 Type B, 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 032/2019/0833, 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 GROUP THE NETHERLANDS B.V. (2797)
SAY BUILDING, JOHN M. KEYNESPLEIN 9, 1066 EP
AMSTERDAM
NETHERLANDS

Guido Van Duren Director - Regulatory affairs Ansell

Place: Brussels Date: 2019/07/25

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:

### **GAMMEX Latex Ortho**

Products manufactured till: [2019/07/24]

PPE to be used against category III risks







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 CE 591640 issued by the Notified Body:

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

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: 2014/01/15