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**<sup>®</sup> Latex Standard

Products manufactured as of: [2022/02/15]

## 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 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 032/2022/0217, 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: 2022/02/15

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**<sup>®</sup> Latex Standard

Products manufactured as of: [2020/03/01] and till: [2022/02/14]

## PPE to be used against category III risks





is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards 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 032/2019/0844, 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: 2020/03/01

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:

# **GAMMEX®** Latex Standard

Products manufactured as of: [2019/07/25] and till: [2020/02/29]

## PPE to be used against category III risks



VIRUS

**EN ISO 374-5** 

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards 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 032/2019/0844, 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 Standard

Products manufactured till: [2019/07/24]

### PPE to be used against category III risks



**KPT** 



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards 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 032/2019/0844, 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