

EU DECLARATION OF CONFORMITY

The Manufacturer

ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM

declares under his sole responsibility, that the PPE described hereafter:

GAMMEX® Non-Latex PI

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

PPE to be used against category III risks

EN ISO 374-1:2016
Type B



KMPT

EN ISO 374-5



VIRUS

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 032/2022/0215, 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

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The Manufacturer

ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM

declares under his sole responsibility, that the PPE described hereafter:

GAMMEX® Non-Latex PI

Products manufactured as of: [2019/11/01] and till: [2022/02/14]

PPE to be used against category III risks



KMPT

EN ISO 374-5



VIRUS

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 032/2019/0854, 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: 2019/11/01

EU DECLARATION OF CONFORMITY

The Manufacturer

ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM

declares under his sole responsibility, that the PPE described hereafter:

GAMMEX® Non-Latex PI

Products manufactured as of: [2019/07/25] and till: [2019/10/31]

PPE to be used against category III risks



KMPT

EN ISO 374-5



VIRUS

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 032/2019/0854, 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

EU DECLARATION OF CONFORMITY

The Manufacturer

ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM

declares under his sole responsibility, that the PPE described hereafter:

GAMMEX® Non-Latex PI

Products manufactured as of: [2019/05/08] and till: [2019/07/24]

PPE to be used against category III risks



KMPT

EN ISO 374-5



VIRUS

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 032/2019/0854, 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: 2019/05/08

EU DECLARATION OF CONFORMITY

The Manufacturer

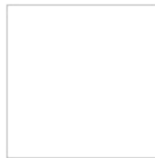
**ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM**

declares under his sole responsibility, that the PPE described hereafter:

Gammex Non-Latex PI

Products manufactured till: [2019/05/07]

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 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