

# 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:

**GAMMEX<sup>®</sup> 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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**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

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

## **GAMMEX<sup>®</sup> Non-Latex PI**

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

**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 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:

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**TECHNOLOGIEPARK 70**  
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**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**



Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2019/11/01

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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:

## **GAMMEX<sup>®</sup> Non-Latex PI**

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

**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 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**

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

## **GAMMEX<sup>®</sup> Non-Latex PI**

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

**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 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

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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 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**