

# 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> PI Plus Glove-in-Glove<sup>™</sup> System**

*Products manufactured as of: [2022/02/09]*

**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 032/2022/0185, 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: 2022/02/09**

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**BOULEVARD INTERNATIONAL 55**  
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**BELGIUM**

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

## **GAMMEX<sup>®</sup> PI Plus Glove-in-Glove<sup>™</sup> System**

*Products manufactured as of: [2020/10/16] and till: [2022/02/08]*

**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 374-1:2016 Type B, EN ISO 374-5:2016, EN 420:2003 + A1:2009 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/0837, issued by the Notified Body:

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**BELGIUM**



**Guido Van Duren**  
**Director - Regulatory affairs**  
**Ansell**

**Place: Brussels**  
**Date: 2020/10/16**

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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> PI Plus Glove-in-Glove<sup>™</sup> System**

*Products manufactured till: [2020/10/15]*

**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 374-1:2016 Type B, EN ISO 374-5:2016, EN 420:2003 + A1:2009 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/0837, issued by the Notified Body:

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**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