

# 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: [25/07/2019]*

**PPE to be used against category III risks**

EN ISO 374-1:2016  
Type B



EN ISO 374-5:2016



**KMPT**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized standards EN 420:2003 + A1:2009, 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 032/2019/0854, 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**

A handwritten signature in black ink, appearing to read "Guido Van Duren".

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 25/07/2019

# 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 Non Latex PI**

*Products manufactured till: [24/07/2019]*

**PPE to be used against category III risks**

**EN 374**



**EN 374**



is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized standards EN 374:2003 Microorganism, EN 374:2003 Low Chemical Resistant, 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**

A handwritten signature in black ink, appearing to read 'Guido Van Duren'.

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 15/01/2014