

## UK 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**

UK Importer  
**ANSELL (U.K.) LIMITED**  
BUILDING C, WILLERBY HILL BUSINESS  
PARK  
WILLERBY, HULL  
**WWW.ANSELL.COM**  
UNITED KINGDOM, HU10 6FE

declare under their sole responsibility, that the PPE described hereafter:

### **GAMMEX® Latex Ortho**

*Applicable Until [2026/02/02]*

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

EN388: 2016



**0010X**

EN ISO 374-1:2016  
Type B



**K P T**

EN ISO 374-5



**VIRUS**

is in conformity with the provisions of Regulation 2016/425 on personal protective equipment, as amended to apply in GB, and with the standards EN 388:2016 +A1:2018, 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 UK Type-examination (Module B, Annex V of the Regulation), under certificate number AB0321/24079-01/E00-00, issued by the Approved Body:

**SATRA TECHNOLOGY CENTRE (0321)  
WYNDHAM WAY, TELFORD WAY,  
KETTERING, NORTHAMPTONSHIRE,  
NN16 8SD, UNITED KINGDOM**

and is subject to the conformity assessment procedure set in out in Annex VIII (Module D) of the Regulation under the surveillance of the Approved Body:

**SATRA TECHNOLOGY CENTRE (0321)  
WYNDHAM WAY, TELFORD WAY,  
KETTERING, NORTHAMPTONSHIRE,  
NN16 8SD, UNITED KINGDOM**



Guido Van Duren  
Director – Regulatory affairs  
Ansell

Place: Brussels  
Date: 2023/04/20

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**ANSELL HEALTHCARE EUROPE N.V.**  
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BOULEVARD INTERNATIONAL 55  
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**WWW.ANSELL.COM**

UK Importer  
**PATIENT GUARD LTD**  
LANCASTER HOUSE,  
AMY JOHNSON WAY,  
BLACKPOOL, LANCASHIRE,  
FY4 2RP, UNITED KINGDOM  
**INFO@PATIENTGUARD.CO.UK**

declare under their sole responsibility, that the PPE described hereafter:

### **GAMMEX™ Latex Ortho** **PPE to be used against category III risks**

is in conformity with the provisions of Regulation 2016/425 on personal protective equipment, as amended to apply in GB, and with the standards and is identical to the PPE which is subject to the Type-examination (Module B, Annex V of the Regulation), under certificate number 032/2026/0052, issued by the Body:

**CENTEXBEL (0493)**  
**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

and is subject to the conformity assessment procedure set in out in Annex VIII (Module D) of the Regulation under the surveillance of the Body:

**CENTEXBEL (0493)**  
**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**



Guido Van Duren  
Director – Regulatory affairs  
Ansell

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Date: 2026/02/03