

# UK DECLARATION OF CONFORMITY

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

and authorized representative:  
**ANSELL (U.K.) LIMITED**  
**BUILDING C, WILLERBY HILL**  
**BUSINESS PARK**  
**WILLERBY, HULL**  
**UNITED KINGDOM, HU10 6FE**

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

## **GAMMEX<sup>®</sup> Latex Ortho**

### **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**