

## **DECLARATION OF CONFORMITY**

This UK Declaration of Conformity is issued under the sole responsibility of Ansell Healthcare Europe NV.

**Manufacturer Name/Address:** Ansell Healthcare Europe NV  
Boulevard International 55,  
Brussels,  
B-1070,  
Belgium

**UK Responsible Person:** Ansell (U.K.) Limited  
Building C,  
Willerby Hill Business Park,  
Willerby, Hull  
HU10 6FE  
United Kingdom

**Risk Class:** Class IIa

**GMDN Code & Definition:** 56293 – Polyisoprene surgical glove, non-powdered,  
non-antimicrobial

**Product Name(s):**

Product Name	Size	External Reference Code
Encore® Non-Latex PI Underglove	5.5	330114055
	6.0	330114060
	6.5	330114065
	7.0	330114070
	7.5	330114075
	8.0	330114080
	8.5	330114085
	9.0	330114090

**Conformity Assessment Procedure:** Part II – Annex V

UKCA Certificate No. 762590

Certified through the British Standards Institution, Approved Body Number 0086.

We hereby declare that the medical device(s) specified above meet the provision of The Medical Devices Regulations 2002 (UK MDR 2002).

Signed on behalf of the Manufacturer



Ansell Healthcare Europe NV  
Riverside Business Park - Block J  
Bld Internationalelaan 55  
B-1070 Brussels  
BELGIUM

Name: Samantha Marshall  
Position: Director Regulatory Affairs Medical EMEA / APAC  
Date: 04 March 2024  
Revision: MED\UKMDR\ENCPOLYISOSURG\002