

## **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 III

**GMDN Code & Definition:** 60951 – Hevea-latex surgical glove, non-powdered, antimicrobial

**Product Name(s):**

Product Name	Size	External Reference Code
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	5.5	353441
	6.0	353442
	6.5	353443
	7.0	353444
	7.5	353445
	8.0	353446
	8.5	353447
	9.0	353448
	5.5	353441A
	6.0	353442A
	6.5	353443A
	7.0	353444A
	7.5	353445A
	8.0	353446A
	8.5	353447A
	9.0	353448A

## Conformity Assessment Procedure:

Part II – Annex II excluding Section 4 (UKCA Certificate No. 762586)

Part II – Annex II Section 4 (UKCA Certificate No. 762589)

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  
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