

Ansell Healthcare Europe NV/SA

Riverside Business Park – Block J

Boulevard International 55

1070 Brussels, Belgium

T. + 32 (0)2 528 74 00

F. + 32 (0)2 528 74 01

Email: info.europe@ansell.com

www.ansell.com



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: 47178 – Hevea-latex surgical glove, non-powdered, non-antimicrobial

Product Name(s):

Product Name	Size	External Reference Code
Gammex® Latex	5.5	330048055
	6.0	330048060
	6.5	330048065
	7.0	330048070
	7.5	330048075
	8.0	330048080
	8.5	330048085
	9.0	330048090

Product Name	Size	External Reference Code
Gammex® Latex EnLite	5.5	330061055
	6	330061060
	6.5	330061065
	7	330061070
	7.5	330061075
	8	330061080
	8.5	330061085
	9	330061090

Product Name	Size	External Reference Code
Gammex® Latex Long Cuff	6	3300011060
	6.5	3300011065
	7	3300011070
	7.5	3300011075
	8	3300011080
	8.5	3300011085
	9	3300011060

Product Name	Size	External Reference Code
Gammex® Latex Micro	5.5	330052055
	6	330052060
	6.5	330052065
	7	330052070
	7.5	330052075
	8	330052080
	8.5	330052085
	9	330052090

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Product Name	Size	External Reference Code
Gammex® Latex Moisturizing	5.5	330049055
	6	330049060
	6.5	330049065
	7	330049070
	7.5	330049075
	8	330049080
	8.5	330049085
	9	330049090

Product Name	Size	External Reference Code
Gammex® Latex Ortho	6	330065060
	6.5	330065065
	7	330065070
	7.5	330065075
	8	330065080
	8.5	330065085
	9	330065090

Product Name	Size	External Reference Code
Gammex® Latex Sensitive	5.5	330051055
	6	330051060
	6.5	330051065
	7	330051070
	7.5	330051075
	8	330051080
	8.5	330051085
	9	330051090

Product Name	Size	External Reference Code
Gammex® Latex Standard	5.5	330085055
	6	330085060
	6.5	330085065
	7	330085070
	7.5	330085075
	8	330085080
	8.5	330085085
	9	330085090

Product Name	Size	External Reference Code
Gammex® Latex Textured	5.5	331300655
	6	331300660
	6.5	331300665
	7	331300670
	7.5	331300675
	8	331300680
	8.5	331300685
	9	331300690

Product Name	Size	External Reference Code
Gammex® Latex Underglove	5.5	330050055
	6	330050060
	6.5	330050065
	7	330050070
	7.5	330050075
	8	330050080
	8.5	330050085
	9	330050090

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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

A handwritten signature in black ink, appearing to read "S. Marshall", written over a horizontal line.

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: 24 March 2022
Revision: MED\UKMDR\GAMNRLSURG\001

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