



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: Nitritex Limited
Ground Floor, 15 Kings Court,
Willie Snaith Road,
Newmarket, Suffolk,
United Kingdom, CB8 7SG

Risk Class: Class IIa

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

Product Name(s):

Product Name	Size	External Reference Code
GAMMEX® Non-Latex PI	5.5	340056055
	6.0	340056060
	6.5	340056065
	7.0	340056070
	7.5	340056075
	8.0	340056080
	8.5	340056085
	9.0	340056090
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GAMMEX® Non-Latex PI Micro	5.5	340057055
	6.0	340057060
	6.5	340057065
	7.0	340057070
	7.5	340057075
	8.0	340057080
	8.5	340057085
	9.0	340057090



Product Name	Size	External Reference Code
GAMMEX® Non-Latex PI Textured	5.5	340054055
	6.0	340054060
	6.5	340054065
	7.0	340054070
	7.5	340054075
	8.0	340054080
	8.5	340054085
	9.0	340054090
GAMMEX® Non-Latex PI Underglove	5.5	340058055
	6.0	340058060
	6.5	340058065
	7.0	340058070
	7.5	340058075
	8.0	340058080
	8.5	340058085
	9.0	340058090
GAMMEX® PI Plus Glove-in-Glove™ System	5.5	340082055
	6.0	340082060
	6.5	340082065
	7.0	340082070
	7.5	340082075
	8.0	340082080
	8.5	340082085
	9.0	340082090
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
Bid Internationaalelaan 55
B-1070 Brussels
BELGIUM

Name: Samantha Marshall
Position: Director Regulatory Affairs Medical
Date: 01 November 2024
Revision: MED\UKMDR\POLYISOSURG\001