

Ansell Healthcare Europe NV/SA

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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: 60857 - Composite-polymer surgical glove, non-powdered

Product Name(s):

Product Name	Size	External Reference Code
Gammex® PI Hybrid	5.5	340063055
	6.0	340063060
	6.5	340063065
	7.0	340063070
	7.5	340063075
	8.0	340063080
	8.5	340063085
	9.0	340063090



Product Name	Size	External Reference Code
Gammex® PI Hybrid Micro	5.5	340002055
	6.0	340002060
	6.5	340002065
	7.0	340002070
	7.5	340002075
	8.0	340002080
	8.5	340002085
	9.0	340002090

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".

Name: Samantha Marshall
Position: Director Regulatory Affairs Medical EMEA / APAC
Date: 24 March 2022
Revision: MED\UKMDR\GAMCOMPOSURG\001

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