

DECLARATION OF CONFORMITY

This declaration is made in accordance with the requirements of Annex VII of the Directive 93/42/EEC

Manufacturer: Ansell Healthcare Europe N.V.

Classification: Class IIa

GMDN Code & Definition: 57970 - Polychloroprene surgical glove, non-powdered

Product Names:

Product Code	Product Description	Size	Region
340006055	Gammex® Non-Latex	5.5	EMEA/ANZ/APAC
340006060	Gammex® Non-Latex	6	EMEA/ANZ/APAC
340006065	Gammex® Non-Latex	6.5	EMEA/ANZ/APAC
340006070	Gammex® Non-Latex	7	EMEA/ANZ/APAC
340006075	Gammex® Non-Latex	7.5	EMEA/ANZ/APAC
340006080	Gammex® Non-Latex	8	EMEA/ANZ/APAC
340006085	Gammex® Non-Latex	8.5	EMEA/ANZ/APAC
340006090	Gammex® Non-Latex	9	EMEA/ANZ/APAC
8511	Gammex® Non-Latex	5.5	NA/India
8512	Gammex® Non-Latex	6	NA/India
8513	Gammex® Non-Latex	6.5	NA/India
8514	Gammex® Non-Latex	7	NA/India
8515	Gammex® Non-Latex	7.5	NA/India
8516	Gammex® Non-Latex	8	NA/India
8517	Gammex® Non-Latex	8.5	NA/India
8518	Gammex® Non-Latex	9	NA/India

Conforms to the applicable essential requirements of Annex I of the Medical Devices Directive 93/42/EEC Official Journal L169 and Directive 2007/47 /EEC.

With production systems certified, where applicable, through the British Standards Institution, Notified Body Number 2797, Certificate Number CE 01537 under Annex V of the Medical Devices Directive 93/42/EEC Official Journal L169 and Directive 2007/47/EEC.

Signed on behalf of the Manufacturer

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

Name: Samantha Marshall
Position: Director Regulatory Affairs Medical EMEA / APAC
Date: 16 June 2021
Version No: MED\GAMNL\003