

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: 47179 – Hevea-latex surgical glove, powdered

Product Names:

Product Code	Product Name	Size	Region
330047055	Gammex® Latex Powdered	5.5	EMEA/INDIA
330047060	Gammex® Latex Powdered	6.0	EMEA/INDIA
330047065	Gammex® Latex Powdered	6.5	EMEA/INDIA
330047070	Gammex® Latex Powdered	7.0	EMEA/INDIA
330047075	Gammex® Latex Powdered	7.5	EMEA/INDIA
330047080	Gammex® Latex Powdered	8.0	EMEA/INDIA
330047085	Gammex® Latex Powdered	8.5	EMEA/INDIA
330047090	Gammex® Latex Powdered	9.0	EMEA/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



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Date: 8th June 2021
Version No: MED\GAMLATPWD\003

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