

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

Brand Names:


Code	Product Description	Size	Region
330048055	Gammex Latex	5.5	EMEA/APAC
330048060	Gammex Latex	6	EMEA/APAC
330048065	Gammex Latex	6.5	EMEA/APAC
330048070	Gammex Latex	7	EMEA/APAC
330048075	Gammex Latex	7.5	EMEA/APAC
330048080	Gammex Latex	8	EMEA/APAC
330048085	Gammex Latex	8.5	EMEA/APAC
330048090	Gammex Latex	9	EMEA/APAC
330048095	Gammex Latex	9.5	EMEA/APAC

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 0086, 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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