

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

Brand Names:

Code	Product Description	Size	Region
340105055	Encore Non-Latex PI Hybrid	5.5	EMEA/ANZ
340105060	Encore Non-Latex PI Hybrid	6	EMEA/ANZ
340105065	Encore Non-Latex PI Hybrid	6.5	EMEA/ANZ
340105070	Encore Non-Latex PI Hybrid	7	EMEA/ANZ
340105075	Encore Non-Latex PI Hybrid	7.5	EMEA/ANZ
340105080	Encore Non-Latex PI Hybrid	8	EMEA/ANZ
340105085	Encore Non-Latex PI Hybrid	8.5	EMEA/ANZ
340105090	Encore Non-Latex PI Hybrid	9	EMEA/ANZ

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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