

## **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, non-antimicrobial

Product Names:

Product Name	Size	External Product Code(s)	Market Regions
GAMMEX® Latex EnLite	5.5	330061055	EMEA
GAMMEX® Latex EnLite	6	330061060	EMEA
GAMMEX® Latex EnLite	6.5	330061065	EMEA
GAMMEX® Latex EnLite	7	330061070	EMEA
GAMMEX® Latex EnLite	7.5	330061075	EMEA
GAMMEX® Latex EnLite	8	330061080	EMEA
GAMMEX® Latex EnLite	8.5	330061085	EMEA
GAMMEX® Latex EnLite	9	330061090	EMEA

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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