

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-microbial

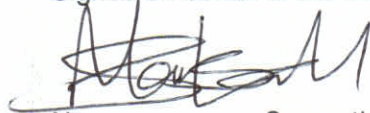
Brand Names:

Code	Product Description	Size	Region
330106060	ENCORE® Latex Ortho	6	EMEA/ANZ
330106065	ENCORE® Latex Ortho	6.5	EMEA/ANZ
330106070	ENCORE® Latex Ortho	7	EMEA/ANZ
330106075	ENCORE® Latex Ortho	7.5	EMEA/ANZ
330106080	ENCORE® Latex Ortho	8	EMEA/ANZ
330106085	ENCORE® Latex Ortho	8.5	EMEA/ANZ
330106090	ENCORE® Latex Ortho	9	EMEA/ANZ
5788001	ENCORE® Latex Ortho	6	NA/LAC
5788002	ENCORE® Latex Ortho	6.5	NA/LAC
5788003	ENCORE® Latex Ortho	7	NA/LAC
5788004	ENCORE® Latex Ortho	7.5	NA/LAC
5788005	ENCORE® Latex Ortho	8	NA/LAC
5788006	ENCORE® Latex Ortho	8.5	NA/LAC
5788007	ENCORE® Latex Ortho	9	NA/LAC

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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