

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 I Sterile

GMDN Code: 59799 - Ethylene Vinyl Acetate Examination/Treatment Glove, Non-Powdered, Sterile

Brand Names:

Code	Product Description	Size	Region
M3330	ETHIPARAT® STERILE	S (PAIRS)	EMEA
M3350	ETHIPARAT® STERILE	M (PAIRS)	EMEA
M3370	ETHIPARAT® STERILE	L PAIRS)	EMEA
M3325	ETHIPARAT® STERILE	S (SINGLE)	EMEA
M3345	ETHIPARAT® STERILE	M (SINGLE)	EMEA
M3365	ETHIPARAT® STERILE	L (SINGLE)	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

As lodged with the Belgian Competent Authority through registration BE/CA01/1-06452-00006-CLI under Article 14(1) of the Medical Devices Directive 93/42/EEC Official Journal L169 and Directive 2007/47/EEC.

For the sterility aspects of the device the production and sterilisation systems are 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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