

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: 56293 – Polyisoprene surgical glove, non-powdered

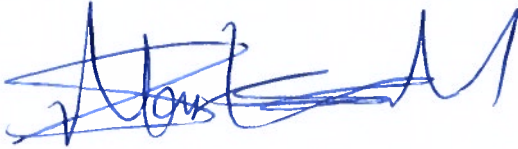
Brand Names:

Code	Product Name	Glove Size	Region
340057055	GAMMEX® Non-Latex PI Micro	5.5	EMEA/ ANZ
340057060	GAMMEX® Non-Latex PI Micro	6	EMEA/ ANZ
340057065	GAMMEX® Non-Latex PI Micro	6.5	EMEA/ ANZ
340057070	GAMMEX® Non-Latex PI Micro	7	EMEA/ ANZ
340057075	GAMMEX® Non-Latex PI Micro	7.5	EMEA/ ANZ
340057080	GAMMEX® Non-Latex PI Micro	8	EMEA/ ANZ
340057085	GAMMEX® Non-Latex PI Micro	8.5	EMEA/ ANZ
340057090	GAMMEX® Non-Latex PI Micro	9	EMEA/ ANZ
20685755	GAMMEX® Non-Latex PI Micro	5.5	NA/LAC
20685760	GAMMEX® Non-Latex PI Micro	6	NA/LAC
20685765	GAMMEX® Non-Latex PI Micro	6.5	NA/LAC
20685770	GAMMEX® Non-Latex PI Micro	7	NA/LAC
20685775	GAMMEX® Non-Latex PI Micro	7.5	NA/LAC
20685780	GAMMEX® Non-Latex PI Micro	8	NA/LAC
20685785	GAMMEX® Non-Latex PI Micro	8.5	NA/LAC
20685790	GAMMEX® Non-Latex PI Micro	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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