Ansell Healthcare Europe NV Riverside Business Park, Block J Bld Internationalelaan 55 B-1070 Brussels Belgium

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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: 59096 Hevea-latex examination/treatment glove, non-powdered sterile

Brand Names:

Code	Product Description	Size	Region
553342	Micro-Touch® Sterile	S	EMEA
553343	Micro-Touch® Sterile	M	EMEA
553344	Micro-Touch® Sterile	L	EMEA
553572	Micro-Touch® Sterile	S	RUSSIA
553573	Micro-Touch® Sterile	M	RUSSIA
553574	Micro-Touch® Sterile	L	RUSSIA

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/CA01/1-06452-00001-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

Ansell Healthcare Europe NV Riverside Business Park - Block J Bld Internationalelaan 55 B-1070 Brussels BELGIUM

Name: Samantha Marshall Position: Associate Director F

Associate Director Regulatory Affairs EMEA & APAC

Date: 9th December 2019 Version No: MED\MTSTERILE\001