

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

GMDN Code: 47176 - Vinyl examination/treatment glove, non-powdered

Brand Names:

Code	Product Description	Size	Region
4001OXS	Synsation™ PF	XS	EMEA
4001OS	Synsation™ PF	S	EMEA
4001OM	Synsation™ PF	M	EMEA
4001OL	Synsation™ PF	L	EMEA
4001OL	Synsation™ PF	L	EMEA
4001OX	Synsation™ PF	XL	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/CA01/1-06452-00004-CLI under Article 14(1) 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 Regulatory Affairs EMEA & APAC
Date: 12th December 2019
Version No: MED\SYNSPF\001