Ansell Healthcare Europe NV/SA
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EU DECLARATION OF CONFORMITY

Manufacturer Name/Address: Ansell Healthcare Europe NV/SA
Riverside Business Park,
Block J, Boulevard International 55,
1070 Brussels,
Belgium

SRN Number: BE-MF-000000691

Risk Class: Class I

Intended Purpose: A non-sterile medical device intended as an examination/treatment glove and a protective barrier when worn on the hands of healthcare providers, during patient examination, or for other sanitary purposes. The device is used mainly as a two-way barrier to protect both the patient and wearer against contaminants. This is a single-use device.

EMDN Code and Description: T010201 – Latex Examination/Treatment Gloves

Basic UDI-DI: 5414566 MTS11U11 YF

Product Name(s):

Product Name	Size	Product Code	Market Regions
Micro-Touch® Sensiclean® II	XS	4566	ANZ
Micro-Touch® Sensiclean® II	S	4560	ANZ
Micro-Touch® Sensiclean® II	M	4562	ANZ
Micro-Touch® Sensiclean® II	L	4564	ANZ
Micro-Touch® Sensiclean® II	XL	4568	ANZ
Micro-Touch® Ultra II	XS	816771	EMEA/ANZ
Micro-Touch® Ultra II	S	816763	EMEA/ANZ
Micro-Touch® Ultra II	M	816767	EMEA/ANZ
Micro-Touch® Ultra II	L	816768	EMEA/ANZ
Micro-Touch® Ultra II	XL	816770	EMEA/ANZ

Conformity Assessment Procedure: Annex I & Annex II + Annex III

This EU Declaration of Conformity is issued under the sole responsibility of Ansell Healthcare Europe NV/SA.

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We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

Signed on behalf of Ansell Healthcare Europe NV

Ansell Healthcare Europe NV
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BELGIUM

Name: Samantha Marshall
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