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: T01020204 - Nitrile Examination/Treatment Glove

Basic UDI-DI: 5414566 MTNITT700 S3

Product Name(s):

Product Name	Size	Product Code	Market Regions
Micro-Touch® Nitra-Tex™	XS	700111	EMEA
Micro-Touch® Nitra-Tex™	S	700112	EMEA
Micro-Touch® Nitra-Tex™	M	700113	EMEA
Micro-Touch® Nitra-Tex™	L	700114	EMEA
Micro-Touch® Nitra-Tex™	XL	700115	EMEA
Micro-Touch® Nitra-Tex™ E.P.	XS	700121	EMEA
Micro-Touch® Nitra-Tex™ E.P.	S	700122	EMEA
Micro-Touch® Nitra-Tex™ E.P.	M	700123	EMEA
Micro-Touch® Nitra-Tex™ E.P.	L	700124	EMEA
Micro-Touch® Nitra-Tex™ E.P.	XL	700125	EMEA

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

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

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
Position: Director Regulatory Affairs Medical EMEA / APAC
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