

## EU DECLARATION OF CONFORMITY

**Manufacturer Name/Address:** Ansell Healthcare Europe NV  
Boulevard International 55  
Brussels  
B-1070  
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

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  
Riverside Business Park - Block J  
Bid Internationaalelaan 55  
B-1070 Brussels  
BELGIUM

Name: Samantha Marshall  
Position: Director Regulatory Affairs Medical  
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