

## 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 MTNF6034 Z5

**Product Name(s):**

Product Name	Size	Product Code	Market Regions
Micro-Touch® Nitrafree™	XS	6034510	EMEA/ANZ
Micro-Touch® Nitrafree™	S	6034511	EMEA/ANZ
Micro-Touch® Nitrafree™	M	6034512	EMEA/ANZ
Micro-Touch® Nitrafree™	L	6034513	EMEA/ANZ
Micro-Touch® Nitrafree™	XL	6034514	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.

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

Ansell Healthcare Europe NV/SA

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Signed on behalf of Ansell Healthcare Europe NV

A handwritten signature in black ink, appearing to read "S. Marshall", is written over a light gray rectangular background.

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