

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 MTNFB3130 AZ

Product Name(s):

Product Name	Size	Product Code	Market Regions
Micro-Touch® Nitrafree™ Blue	XS	313028060	NA
Micro-Touch® Nitrafree™ Blue	S	313028070	NA
Micro-Touch® Nitrafree™ Blue	M	313028080	NA
Micro-Touch® Nitrafree™ Blue	L	313028090	NA
Micro-Touch® Nitrafree™ Blue	XL	313028100	NA
Micro-Touch® Nitrafree™ Blue	S-L 6PC SP	313028000-SAMP	NA

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



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BELGIUM

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Date of issue: 02 March 2023
Place of issue: Nuneaton, England
Version No: MED\MTNITFREEBLU\003