Ansell Healthcare Europe NV/SA
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1070 Brussels, Belgium

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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: T010201 – Latex Examination / Treatment Gloves

Basic UDI-DI: 5414566 MTCT553 WB

Product Name(s):

Product Name	Product Code	Size	Region
MICRO-TOUCH® Coated	553301	XS	EMEA
MICRO-TOUCH® Coated	553302	S	EMEA
MICRO-TOUCH® Coated	553303	M	EMEA
MICRO-TOUCH® Coated	553304	L	EMEA
MICRO-TOUCH® Coated	553305	XL	EMEA
MICRO-TOUCH® Coated	303036XS	XS	Kuwait
MICRO-TOUCH® Coated	303036SM	S	Kuwait
MICRO-TOUCH® Coated	303036MD	M	Kuwait
MICRO-TOUCH® Coated	303036LG	L	Kuwait
MICRO-TOUCH® Coated	303001XS	XS	APAC-China
MICRO-TOUCH® Coated	303001SM	S	APAC-China
MICRO-TOUCH® Coated	303001MD	M	APAC-China

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MICRO-TOUCH® Coated	303001LG	L	APAC-China
MICRO-TOUCH® Coated	303001XL	XL	APAC-China

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.

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 the Manufacturer

Ansell Healthcare Europe NV
Riverside Business Park - Block J
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B-1070 Brussels
BELGIUM

Name: Samantha Marshall
Position: Director Regulatory Affairs Medical
Date of issue: 19 June 2024
Place of issue: Nuneaton, England
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