Ansell Healthcare Europe NV/SA
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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: T01020204 - Nitrile Examination/Treatment Glove

Basic UDI-DI: 5414566 MF92134 DK

Product Name(s):

Product Name	Size	Product Code	Market Regions
MICROFLEX® 92-134 Versatility	XS	92134060	EMEA/APAC
MICROFLEX® 92-134 Versatility	S	92134070	EMEA/APAC
MICROFLEX® 92-134 Versatility	M	92134080	EMEA/APAC
MICROFLEX® 92-134 Versatility	L	92134090	EMEA/APAC
MICROFLEX® 92-134 Versatility	XL	92134100	EMEA/APAC
MICROFLEX® 92-134 Versatility	XXL	92134110	EMEA/APAC
MICRO-TOUCH® Blue Nitrile	XS	313041060	EMEA/APAC
MICRO-TOUCH® Blue Nitrile	S	313041065	EMEA/APAC
MICRO-TOUCH® Blue Nitrile	M	313041070	EMEA/APAC
MICRO-TOUCH® Blue Nitrile	L	313041075	EMEA/APAC
MICRO-TOUCH® Blue Nitrile	XL	313041080	EMEA/APAC

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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 Ansell Healthcare Europe NV

Ansell Healthcare Europe NV
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BELGIUM

Name:	Samantha Marshall
Position:	Director Regulatory Affairs Medical
Date of issue:	18 November 2024
Place of issue:	Nuneaton, England
Version No:	MED\MFX92134MTBLUNIT\003