Ansell Healthcare Europe NV/SA
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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 MF92134 DK

Product Name(s):

Product Name	Size	Product Code	Market Regions
Microflex® 92-134	XS	92134060	EMEA/INDIA
Microflex® 92-134	S	92134070	EMEA/INDIA
Microflex® 92-134	M	92134080	EMEA/INDIA
Microflex® 92-134	L	92134090	EMEA/INDIA
Microflex® 92-134	XL	92134100	EMEA/INDIA
Micro-Touch® Blue Nitrile	XS	313041060	EMEA/ANZ
Micro-Touch® Blue Nitrile	S	313041065	EMEA/ANZ
Micro-Touch® Blue Nitrile	M	313041070	EMEA/ANZ
Micro-Touch® Blue Nitrile	L	313041075	EMEA/ANZ
Micro-Touch® Blue Nitrile	XL	313041080	EMEA/ANZ

Conformity Assessment Procedure: Annex I & Annex II + Annex III

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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
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BELGIUM

Name: Samantha Marshall
Position: Director Regulatory Affairs Medical EMEA / APAC
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