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 MF93853 EZ

Product Name(s):

Product Name	Size	Product Code	Market Regions
Microflex® 93-853	XS	93853060	EMEA, APAC
Microflex® 93-853	S	93853070	EMEA, APAC
Microflex® 93-853	M	93853080	EMEA, APAC
Microflex® 93-853	L	93853090	EMEA, APAC
Microflex® 93-853	XL	93853100	EMEA, APAC
Microflex® 93-853	XXL	93853110	EMEA, APAC
Microflex® 93-853	XXXL	93853120	EMEA, APAC

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.

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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
Date of issue:	02 March 2023
Place of issue:	Nuneaton, England
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