Ansell Healthcare Europe NV/SA
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EU DECLARATION OF CONFORMITY

Manufacturer Name/Address: Ansell Healthcare Europe NV/SA
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 MF63893 EC

Product Name(s):

Product Name	Size	Product Code	Market Regions
Microflex® 63-893	S	63893070	ANZ/APAC
Microflex® 63-893	M	63893080	ANZ/APAC
Microflex® 63-893	L	63893090	ANZ/APAC
Microflex® 63-893	XL	63893100	ANZ/APAC
Microflex® Safegrip	S	SG-375-S	ANZ
Microflex® Safegrip	M	SG-375-M	ANZ
Microflex® Safegrip	L	SG-375-L	ANZ
Microflex® Safegrip	XL	SG-375-XL	ANZ

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.

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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 EMEA / APAC
Date of issue: 16 November 2023
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