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: T010201 – Latex Examination / Treatment Gloves

Basic UDI-DI: 5414566 MTDC045MF63854 SG

Product Name(s):

Product Brand Name	Size	External Reference Code	Market Regions
Microflex® 63-854	XS	63854060	APAC/ANZ/JAPAN
Microflex® 63-854	S	63854070	APAC/ANZ/JAPAN
Microflex® 63-854	M	63854080	APAC/ANZ/JAPAN
Microflex® 63-854	L	63854090	APAC/ANZ/JAPAN
Microflex® 63-854	XL	63854100	APAC/ANZ/JAPAN
Microflex® 63-854	Mixed sizes	63854000-SAMP	APAC/ANZ/JAPAN
Micro-Touch® Dermaclean®	XS	04570	EMEA/APAC-ANZ/APAC-China
Micro-Touch® Dermaclean®	S	04572	EMEA/APAC-ANZ/APAC-China

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Micro-Touch® Dermaclean®	M	04574	EMEA/APAC-ANZ/APAC-China
Micro-Touch® Dermaclean®	L	04576	EMEA/APAC-ANZ/APAC-China
Micro-Touch® Dermaclean®	XL	04578	EMEA/APAC-ANZ/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/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 the Manufacturer

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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Place of issue: Nuneaton, England
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