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 MTCT553 WB

Product Name(s):

Code	Product Description	Size	Region
553301	Micro-Touch® Coated	XS	EMEA
553302	Micro-Touch® Coated	S	EMEA
553303	Micro-Touch® Coated	M	EMEA
553304	Micro-Touch® Coated	L	EMEA
553305	Micro-Touch® Coated	XL	EMEA
553601	Micro-Touch® Coated	XS	RUSSIA
553602	Micro-Touch® Coated	S	RUSSIA
553603	Micro-Touch® Coated	M	RUSSIA
553604	Micro-Touch® Coated	L	RUSSIA
553605	Micro-Touch® Coated	XL	RUSSIA

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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/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
Bld Internationalelaan 55
B-1070 Brussels
BELGIUM

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