Ansell Healthcare Europe NV/SA
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EU DECLARATION OF CONFORMITY

This EU Declaration of Conformity is issued under the sole responsibility of Ansell Healthcare Europe NV.

Manufacturer Name/Address: Ansell Healthcare Europe NV
Boulevard International 55
Brussels
B-1070
Belgium

SRN Number: BE-MF-000000691

Risk Class: Class Is

Intended Purpose: A 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 Glove

Basic UDI-DI: 5414566 MTS553DS550 5Q

Product Name(s):

Product Description	Code	Size	Market Region
Micro-Touch® Sterile	553342	S	EMEA
Micro-Touch® Sterile	553343	M	EMEA
Micro-Touch® Sterile	553344	L	EMEA

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

For the sterility aspects of the device these are certified through the British Standards Institution, Notified Body Number 2797, Certificate MDR 763361 under Annex IX Chapters I & III.

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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 the Manufacturer

Ansell Healthcare Europe NV
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BELGIUM

Name: Samantha Marshall
Position: Director Regulatory Affairs Medical
Date of issue: 05 March 2025
Place of issue: Nuneaton, England
Version No: MED\MDR\MTST\002