Ansell Healthcare Europe NV/SA
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Riverside Business Park – Block J
Boulevard International 55
1070 Brussels, Belgium

T. + 32 (0)2 528 74 00
F. + 32 (0)2 528 74 01
Email: info.europe@ansell.com
www.ansell.com

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: T01020203 – Polychloroprene Examination/Treatment Gloves

Basic UDI-DI: 5414566 MTA553 RE

Product Name(s):

Product Name	Size	Product Code	Market Regions
Micro-Touch® Affinity	M	553353	EMEA/ANZ
Micro-Touch® Affinity	S	553352	EMEA/ANZ
Micro-Touch® Affinity	XL	553355	EMEA/ANZ
Micro-Touch® Affinity	L	553354	EMEA/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.

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
Bld Internationalelaan 55
B-1070 Brussels
BELGIUM

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