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 IIa

Intended Purpose: A sterile medical device intended as a surgical glove and a protective barrier when worn on the hands of healthcare providers at the surgical site. It is used mainly as a two-way barrier to protect patient and staff from microorganisms. This is a single-use device.

EMDN Code and Description: T01010102 - Non-Powdered Latex Surgical Gloves

Basic UDI DI: 5414566 MGLPFSH333581 4H

Product Name(s):

Product Name	Product Code	Size	Region(s)
Medi-Grip® Latex Powder Free	330200955	5.5	Italy
Medi-Grip® Latex Powder Free	330200960	6.0	Italy
Medi-Grip® Latex Powder Free	330200965	6.5	Italy
Medi-Grip® Latex Powder Free	330200970	7.0	Italy
Medi-Grip® Latex Powder Free	330200975	7.5	Italy
Medi-Grip® Latex Powder Free	330200980	8.0	Italy
Medi-Grip® Latex Powder Free	330200985	8.5	Italy
Medi-Grip® Latex Powder Free	330200990	9.0	Italy
Medi-Grip® Latex Powder Free	354101	5.5	EMEA/APAC
Medi-Grip® Latex Powder Free	354102	6.0	EMEA/APAC
Medi-Grip® Latex Powder Free	354103	6.5	EMEA/APAC
Medi-Grip® Latex Powder Free	354104	7.0	EMEA/APAC
Medi-Grip® Latex Powder Free	354105	7.5	EMEA/APAC
Medi-Grip® Latex Powder Free	354106	8.0	EMEA/APAC

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Product Name	Product Code	Size	Region(s)
Medi-Grip® Latex Powder Free	354107	8.5	EMEA/APAC
Medi-Grip® Latex Powder Free	354108	9.0	EMEA/APAC
Medi-Grip® Latex Powder Free	8155MG	5.5	Japan
Medi-Grip® Latex Powder Free	8160MG	6	Japan
Medi-Grip® Latex Powder Free	8165MG	6.5	Japan
Medi-Grip® Latex Powder Free	8170MG	7	Japan
Medi-Grip® Latex Powder Free	8175MG	7.5	Japan
Medi-Grip® Latex Powder Free	8180MG	8	Japan
Medi-Grip® Latex Powder Free	8185MG	8.5	Japan

Conformity Assessment Procedure: Annex IX.

CE Certificate No: MDR 763361.

Certified through the British Standards Institution, Notified Body Number 2797.

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
Date: 02 March 2023
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