

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 MGLSTD3302 YR
Product Name(s):	

Product Name	Product Code	Size	Region(s)
Medi-Grip® Latex Standard Surgical Glove	330200755	5.5	EMEA
Medi-Grip® Latex Standard Surgical Glove	330200760	6.0	EMEA
Medi-Grip® Latex Standard Surgical Glove	330200765	6.5	EMEA
Medi-Grip® Latex Standard Surgical Glove	330200770	7.0	EMEA
Medi-Grip® Latex Standard Surgical Glove	330200775	7.5	EMEA
Medi-Grip® Latex Standard Surgical Glove	330200780	8.0	EMEA
Medi-Grip® Latex Standard Surgical Glove	330200785	8.5	EMEA
Medi-Grip® Latex Standard Surgical Glove	330200790	9.0	EMEA
Medi-Grip® Latex Standard Surgical Glove	330200755	5.5	SEA/China
Medi-Grip® Latex Standard Surgical Glove	330200760	6.0	SEA/China
Medi-Grip® Latex Standard Surgical Glove	330200765	6.5	SEA/China
Medi-Grip® Latex Standard Surgical Glove	330200770	7.0	SEA/China
Medi-Grip® Latex Standard Surgical Glove	330200775	7.5	SEA/China
Medi-Grip® Latex Standard Surgical Glove	330200780	8.0	SEA/China



Product Name	Product Code	Size	Region(s)
Medi-Grip® Latex Standard Surgical Glove	330200785	8.5	SEA/China
Medi-Grip® Latex Standard Surgical Glove	330200790	9.0	SEA/China
Medi-Grip® Latex Standard Surgical Glove	330200755	5.5	India
Medi-Grip® Latex Standard Surgical Glove	330200760	6.0	India
Medi-Grip® Latex Standard Surgical Glove	330200765	6.5	India
Medi-Grip® Latex Standard Surgical Glove	330200770	7.0	India
Medi-Grip® Latex Standard Surgical Glove	330200775	7.5	India
Medi-Grip® Latex Standard Surgical Glove	330200780	8.0	India
Medi-Grip® Latex Standard Surgical Glove	330200785	8.5	India
Medi-Grip® Latex Standard Surgical Glove	330200790	9.0	India

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
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 B-1070 Brussels
 BELGIUM

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