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

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 and risk of allergy to latex. This is a single-use device.

EMDN Code and Description: T01010203 Polyisoprene Surgical Gloves

Basic UDI DI: 5414566 GNLPIMIC340206 3S

Product Name(s):

Product Name	Product Code	Size	Region(s)
GAMMEX® Non-Latex PI Micro	340057055	5.5	EMEA/ANZ/APAC-SEA
GAMMEX® Non-Latex PI Micro	340057060	6.0	EMEA/ANZ/APAC-SEA
GAMMEX® Non-Latex PI Micro	340057065	6.5	EMEA/ANZ/APAC-SEA
GAMMEX® Non-Latex PI Micro	340057070	7.0	EMEA/ANZ/APAC-SEA
GAMMEX® Non-Latex PI Micro	340057075	7.5	EMEA/ANZ/APAC-SEA
GAMMEX® Non-Latex PI Micro	340057080	8.0	EMEA/ANZ/APAC-SEA
GAMMEX® Non-Latex PI Micro	340057085	8.5	EMEA/ANZ/APAC-SEA
GAMMEX® Non-Latex PI Micro	340057090	9.0	EMEA/ANZ/APAC-SEA
GAMMEX® Non-Latex PI Micro	20685755	5.5	NA/LAC
GAMMEX® Non-Latex PI Micro	20685760	6.0	NA/LAC
GAMMEX® Non-Latex PI Micro	20685765	6.5	NA/LAC
GAMMEX® Non-Latex PI Micro	20685770	7.0	NA/LAC
GAMMEX® Non-Latex PI Micro	20685775	7.5	NA/LAC
GAMMEX® Non-Latex PI Micro	20685780	8.0	NA/LAC

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GAMMEX® Non-Latex PI Micro	340057055	5.5	Japan
GAMMEX® Non-Latex PI Micro	340057060	6.0	Japan
GAMMEX® Non-Latex PI Micro	340057065	6.5	Japan
GAMMEX® Non-Latex PI Micro	340057070	7.0	Japan
GAMMEX® Non-Latex PI Micro	340057075	7.5	Japan
GAMMEX® Non-Latex PI Micro	340057080	8.0	Japan
GAMMEX® Non-Latex PI Micro	340057085	8.5	Japan
GAMMEX® Non-Latex PI Micro	340057090	9.0	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
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