

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 GNLPI34002068 7G

Product Name(s):

Product Name	Product Code	Size	Region(s)
Gammex ® Non-Latex PI	340056055	5.5	EMEA, ANZ, JAPAN
Gammex ® Non-Latex PI	340056060	6.0	EMEA, ANZ, JAPAN
Gammex ® Non-Latex PI	340056065	6.5	EMEA, ANZ, JAPAN
Gammex ® Non-Latex PI	340056070	7.0	EMEA, ANZ, JAPAN
Gammex ® Non-Latex PI	340056075	7.5	EMEA, ANZ, JAPAN
Gammex ® Non-Latex PI	340056080	8.0	EMEA, ANZ, JAPAN
Gammex ® Non-Latex PI	340056085	8.5	EMEA, ANZ, JAPAN
Gammex ® Non-Latex PI	340056090	9.0	EMEA & ANZ
Gammex ® Non-Latex PI	20685755	5.5	NA/LAC
Gammex ® Non-Latex PI	20685760	6.0	NA/LAC
Gammex ® Non-Latex PI	20685765	6.5	NA/LAC
Gammex ® Non-Latex PI	20685770	7.0	NA/LAC

Product Name	Product Code	Size	Region(s)
Gammex ® Non-Latex PI	20685775	7.5	NA/LAC
Gammex ® Non-Latex PI	20685780	8.0	NA/LAC
Gammex ® Non-Latex PI	20685785	8.5	NA/LAC
Gammex ® Non-Latex PI	20685790	9.0	NA/LAC

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
Place of Issue: Nuneaton, England
Revision: MED\MDR\GAMNLP\001