

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 III

Intended Purpose: A sterile medical device intended as a surgical glove and intended 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: T010199 – Surgical Gloves – Other

Basic UDI DI: 5414566 GPFAMT3534 Q2

Product Name(s):

Product Name	Product Code	Size	Region
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353441	5.5	EMEA
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353442	6.0	EMEA
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353443	6.5	EMEA
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353444	7.0	EMEA
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353445	7.5	EMEA
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353446	8.0	EMEA
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353447	8.5	EMEA
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353448	9.0	EMEA
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353441A	5.5	EMEA
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353442A	6.0	EMEA
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353443A	6.5	EMEA

Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353444A	7.0	EMEA
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353445A	7.5	EMEA
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353446A	8.0	EMEA
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353447A	8.5	EMEA
Gammex® Powder-Free with AMT™ Antimicrobial Technology Surgical Glove	353448A	9.0	EMEA

Conformity Assessment Procedure:

Annex IX Chapters I & III - CE Certificate No. MDR 763361

Annex IX Chapter II - CE Certificate No. MDR 763362

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



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BELGIUM

Name: Samantha Marshall
Position: Director Regulatory Affairs Medical EMEA / APAC
Date: 05th February 2024
Place: Nuneaton, England
Version No: MED\EU\GAMAMTNRL\002