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 III

Intended Purpose: A sterile medical device intended to be worn by healthcare personnel to reduce the risk of microbial contamination to the user and protect a surgical wound from contamination. 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

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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:

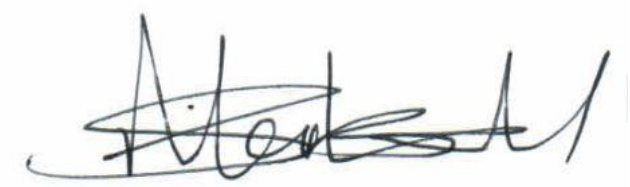
Annex IX Chapters I & III - CE Certificate No. MDR 763361

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



Ansell Healthcare Europe NV
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BELGIUM

Name: Samantha Marshall
Position: Director Regulatory Affairs Medical
Date: 21 May 2024
Place: Nuneaton, England
Version No: MED\EU\GAMAMTNRL\004

By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 763362 R000

Manufacturer: Ansell Healthcare Europe NV

Address:
Boulevard International 55
Brussels, B-1070
Belgium

Single Registration Number: BE-MF-000000691

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-01-17**

Current Issue Date: **2025-05-28**

Starting Validity Date: **2025-05-28**

Expiry Date: **2029-01-16**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 763362 R000

Device Schedule:

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
Natural Rubber Latex Sterile Powder Free Antimicrobial Surgical Glove	Gammex PF with AMT Antimicrobial Technology	MDN1214	To prevent cross contamination from microbes and body fluids between the patient and wearer	Class III	5414566 GPFAMT3534 Q2

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 763362 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2024-01-17	3598563	Issued
Current	30249302	Amended – Addition of crucial supplier Removal of crucial supplier

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