

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 GLAT330048 62

Product Name(s):

Product Name	Product Code	Size	Region(s)
Gammex® Latex	330048055	5.5	EMEA/APAC
Gammex® Latex	330048060	6	EMEA/APAC
Gammex® Latex	330048065	6.5	EMEA/APAC
Gammex® Latex	330048070	7	EMEA/APAC
Gammex® Latex	330048075	7.5	EMEA/APAC
Gammex® Latex	330048080	8	EMEA/APAC
Gammex® Latex	330048085	8.5	EMEA/APAC
Gammex® Latex	330048090	9	EMEA/APAC
Gammex® Latex	330048095	9.5	EMEA/APAC

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\GAMLAT\001

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 763361 R000

Manufacturer: Ansell Healthcare Europe NV

Address:

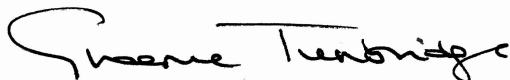
Boulevard International 55
Brussels, B-1070
Belgium

Single Registration Number: BE-MF-000000691

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II 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: **2023-01-05**

Current Issue Date: **2025-02-10**

Starting Validity Date: **2025-02-10**

Expiry Date: **2028-01-04**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 763361 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Natural rubber latex powder free sterile surgical gloves	Class IIa
Synthetic polyisoprene powder free sterile surgical gloves	Class IIa
Polychloroprene powder free sterile surgical gloves	Class IIa
Composite polymer (polyisoprene + Polychloroprene) powder free sterile surgical gloves	Class IIa
Radiation attenuating polyisoprene powder free sterile surgical gloves	Class IIa
Natural rubber latex glove-in-glove system powder free sterile surgical gloves	Class IIa
Synthetic polyisoprene glove-in-glove system powder free sterile surgical gloves	Class IIa
Nitrile powder free sterile examination gloves	Class Is
Natural rubber latex powder free sterile examination gloves	Class Is
Copolymer powder free sterile examination gloves	Class Is
Sterile Skin Markers	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Natural Rubber Latex Sterile Powder Free Antimicrobial Surgical Glove	See MDR 763362

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EU Quality Management System Certificate

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MDR 763361 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
2023-01-05	3598363	Issued
2023-05-10	30000150	Amended ; <ul style="list-style-type: none"> - Addition of two new sub-contractors - Company name change for a subcontractor - Administrative changes to Device Name in Device Schedule
2024-01-17	30073390	Supplemented – Addition of Natural Rubber Latex Sterile Powder Free Antimicrobial Surgical Glove device.
Current	30297139	Supplemented – Addition of Sterile Skin Markers into the certificate. Amended – Addition of critical sub-contractor.

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