

## **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  
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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 GLGIG330083 NZ

**Product Name(s):**

Product Name	Product Code	Size	Region(s)
GAMMEX® Latex Glove-in-Glove™ System	330083055	5.5	EMEA/ANZ/SEA/China
GAMMEX® Latex Glove-in-Glove™ System	330083060	6	EMEA/ANZ/SEA/China
GAMMEX® Latex Glove-in-Glove™ System	330083065	6.5	EMEA/ANZ/SEA/China
GAMMEX® Latex Glove-in-Glove™ System	330083070	7	EMEA/ANZ/SEA/China
GAMMEX® Latex Glove-in-Glove™ System	330083075	7.5	EMEA/ANZ/SEA/China
GAMMEX® Latex Glove-in-Glove™ System	330083080	8	EMEA/ANZ/SEA/China
GAMMEX® Latex Glove-in-Glove™ System	330083085	8.5	EMEA/ANZ/SEA/China
GAMMEX® Latex Glove-in-Glove™ System	330083090	9	EMEA/ANZ/SEA/China

**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



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