

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 GLSEN33005 KE

Product Name(s):

| Product Name | Product Code | Size | Region(s) |
|-------------------------|--------------|------|---------------|
| GAMMEX® Latex Sensitive | 330051055 | 5.5 | EMEA/APAC/ANZ |
| GAMMEX® Latex Sensitive | 330051060 | 6 | EMEA/APAC/ANZ |
| GAMMEX® Latex Sensitive | 330051065 | 6.5 | EMEA/APAC/ANZ |
| GAMMEX® Latex Sensitive | 330051070 | 7 | EMEA/APAC/ANZ |
| GAMMEX® Latex Sensitive | 330051075 | 7.5 | EMEA/APAC/ANZ |
| GAMMEX® Latex Sensitive | 330051080 | 8 | EMEA/APAC/ANZ |
| GAMMEX® Latex Sensitive | 330051085 | 8.5 | EMEA/APAC/ANZ |
| GAMMEX® Latex Sensitive | 330051090 | 9 | EMEA/APAC/ANZ |

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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