

## **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 and risk of allergy to latex. This is a single-use device.

**EMDN Code and Description:** T01010203 Polyisoprene Surgical Gloves

**Basic UDI DI:** 5414566 GNLPI34002068 7G

**Product Name(s):**

| Product Name          | Product Code | Size | Region(s)        |
|-----------------------|--------------|------|------------------|
| Gammex ® Non-Latex PI | 340056055    | 5.5  | EMEA, ANZ, JAPAN |
| Gammex ® Non-Latex PI | 340056060    | 6.0  | EMEA, ANZ, JAPAN |
| Gammex ® Non-Latex PI | 340056065    | 6.5  | EMEA, ANZ, JAPAN |
| Gammex ® Non-Latex PI | 340056070    | 7.0  | EMEA, ANZ, JAPAN |
| Gammex ® Non-Latex PI | 340056075    | 7.5  | EMEA, ANZ, JAPAN |
| Gammex ® Non-Latex PI | 340056080    | 8.0  | EMEA, ANZ, JAPAN |
| Gammex ® Non-Latex PI | 340056085    | 8.5  | EMEA, ANZ, JAPAN |
| Gammex ® Non-Latex PI | 340056090    | 9.0  | EMEA & ANZ       |
|                       |              |      |                  |
| Gammex ® Non-Latex PI | 20685755     | 5.5  | NA/LAC           |
| Gammex ® Non-Latex PI | 20685760     | 6.0  | NA/LAC           |
| Gammex ® Non-Latex PI | 20685765     | 6.5  | NA/LAC           |
| Gammex ® Non-Latex PI | 20685770     | 7.0  | NA/LAC           |

| Product Name          | Product Code | Size | Region(s) |
|-----------------------|--------------|------|-----------|
| Gammex ® Non-Latex PI | 20685775     | 7.5  | NA/LAC    |
| Gammex ® Non-Latex PI | 20685780     | 8.0  | NA/LAC    |
| Gammex ® Non-Latex PI | 20685785     | 8.5  | NA/LAC    |
| Gammex ® Non-Latex PI | 20685790     | 9.0  | NA/LAC    |

**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  
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