

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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Brussels
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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 ELOGLO330578 TZ

Product Name(s):

Product Name	Product Code	Size	Region(s)
GAMMEX® Latex Ortho	330065060	6	EMEA/ANZ
GAMMEX® Latex Ortho	330065065	6.5	EMEA/ANZ
GAMMEX® Latex Ortho	330065070	7	EMEA/ANZ
GAMMEX® Latex Ortho	330065075	7.5	EMEA/ANZ
GAMMEX® Latex Ortho	330065080	8	EMEA/ANZ
GAMMEX® Latex Ortho	330065085	8.5	EMEA/ANZ
GAMMEX® Latex Ortho	330065090	9	EMEA/ANZ
ENCORE® Latex Ortho	5788001	6	NA/LAC
ENCORE® Latex Ortho	5788002	6.5	NA/LAC
ENCORE® Latex Ortho	5788003	7	NA/LAC
ENCORE® Latex Ortho	5788004	7.5	NA/LAC
ENCORE® Latex Ortho	5788005	8	NA/LAC
ENCORE® Latex Ortho	5788006	8.5	NA/LAC

ENCORE® Latex Ortho	5788007	9	NA/LAC
ENCORE® Latex Ortho	330106060	6	EMEA/ANZ
ENCORE® Latex Ortho	330106065	6.5	EMEA/ANZ
ENCORE® Latex Ortho	330106070	7	EMEA/ANZ
ENCORE® Latex Ortho	330106075	7.5	EMEA/ANZ
ENCORE® Latex Ortho	330106080	8	EMEA/ANZ
ENCORE® Latex Ortho	330106085	8.5	EMEA/ANZ
ENCORE® Latex Ortho	330106090	9	EMEA/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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