

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 ELTEXT330578 8Y

Product Name(s):

Product Name	Product Code	Size	Region(s)
ENCORE® Latex Textured	330101055	5.5	EMEA
ENCORE® Latex Textured	330101060	6	EMEA
ENCORE® Latex Textured	330101065	6.5	EMEA
ENCORE® Latex Textured	330101070	7	EMEA
ENCORE® Latex Textured	330101075	7.5	EMEA
ENCORE® Latex Textured	330101080	8	EMEA
ENCORE® Latex Textured	330101085	8.5	EMEA
ENCORE® Latex Textured	330101090	9	EMEA
ENCORE® Latex Textured	5785000	5.5	NA/LAC
ENCORE® Latex Textured	5785001	6	NA/LAC
ENCORE® Latex Textured	5785002	6.5	NA/LAC
ENCORE® Latex Textured	5785003	7	NA/LAC
ENCORE® Latex Textured	5785004	7.5	NA/LAC
ENCORE® Latex Textured	5785005	8	NA/LAC
ENCORE® Latex Textured	5785006	8.5	NA/LAC
ENCORE® Latex Textured	5785007	9	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



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