Ansell Healthcare Europe NV/SA
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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. This is a single-use device.

EMDN Code and Description: T01010102 - Non-Powdered Latex Surgical Gloves

Basic UDI DI: 5414566 ELUNG33012018 7E

Product Name(s):

Product Name	Product Code	Size	Region(s)
ENCORE® Latex Underglove	330113055	5.5	EMEA
ENCORE® Latex Underglove	330113060	6	EMEA
ENCORE® Latex Underglove	330113065	6.5	EMEA
ENCORE® Latex Underglove	330113070	7	EMEA
ENCORE® Latex Underglove	330113075	7.5	EMEA
ENCORE® Latex Underglove	330113080	8	EMEA
ENCORE® Latex Underglove	330113085	8.5	EMEA
ENCORE® Latex Underglove	330113090	9	EMEA
ENCORE® Latex Underglove	2018455	5.5	NA
ENCORE® Latex Underglove	2018460	6	NA
ENCORE® Latex Underglove	2018465	6.5	NA
ENCORE® Latex Underglove	2018470	7	NA
ENCORE® Latex Underglove	2018475	7.5	NA

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ENCORE® Latex Underglove	2018480	8	NA
ENCORE® Latex Underglove	2018485	8.5	NA
ENCORE® Latex Underglove	2018490	9	NA

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
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BELGIUM

Name: Samantha Marshall
Position: Director Regulatory Affairs Medical EMEA & APAC
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