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 ELMIC33015787 SH

Product Name(s):

Product Name	Product Code	Size	Region(s)
ENCORE® Latex Micro	330104055	5.5	EMEA/APAC
ENCORE® Latex Micro	330104060	6	EMEA/APAC
ENCORE® Latex Micro	330104065	6.5	EMEA/APAC
ENCORE® Latex Micro	330104070	7	EMEA/APAC
ENCORE® Latex Micro	330104075	7.5	EMEA/APAC
ENCORE® Latex Micro	330104080	8	EMEA/APAC
ENCORE® Latex Micro	330104085	8.5	EMEA/APAC
ENCORE® Latex Micro	330104090	9	EMEA/APAC
ENCORE® Latex Micro	5787000	5.5	NA/LAC/APAC
ENCORE® Latex Micro	5787001	6	NA/LAC/APAC
ENCORE® Latex Micro	5787002	6.5	NA/LAC/APAC
ENCORE® Latex Micro	5787003	7	NA/LAC/APAC
ENCORE® Latex Micro	5787004	7.5	NA/LAC/APAC
ENCORE® Latex Micro	5787005	8	NA/LAC/APAC

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Product Name	Product Code	Size	Region(s)
ENCORE® Latex Micro	5787006	8.5	NA/LAC/APAC
ENCORE® Latex Micro	5787007	9	NA/LAC/APAC
ENCORE® Latex Micro	5787000	5.5	INDIA
ENCORE® Latex Micro	5787001	6	INDIA
ENCORE® Latex Micro	5787002	6.5	INDIA
ENCORE® Latex Micro	5787003	7	INDIA
ENCORE® Latex Micro	5787004	7.5	INDIA
ENCORE® Latex Micro	5787005	8	INDIA
ENCORE® Latex Micro	5787006	8.5	INDIA
ENCORE® Latex Micro	5787007	9	INDIA
ENCORE® Latex Micro	330104060	6	BRAZIL
ENCORE® Latex Micro	330104065	6.5	BRAZIL
ENCORE® Latex Micro	330104070	7	BRAZIL
ENCORE® Latex Micro	330104075	7.5	BRAZIL
ENCORE® Latex Micro	330104080	8	BRAZIL
ENCORE® Latex Micro	330104085	8.5	BRAZIL

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
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B-1070 Brussels
BELGIUM

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