Ansell Healthcare Europe NV/SA
—
Riverside Business Park – Block J
Boulevard International 55
1070 Brussels, Belgium

T. + 32 (0)2 528 74 00
F. + 32 (0)2 528 74 01
Email: info.europe@ansell.com
www.ansell.com

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 ELAC57FTGLS33 9V

Product Name(s):

Product Name	Product Code	Size	Region(s)
Encore® Latex Acclaim®	5795000	5.5	NA/LAC
Encore® Latex Acclaim®	5795001	6.0	NA/LAC
Encore® Latex Acclaim®	5795002	6.5	NA/LAC
Encore® Latex Acclaim®	5795003	7.0	NA/LAC
Encore® Latex Acclaim®	5795004	7.5	NA/LAC
Encore® Latex Acclaim®	5795005	8.0	NA/LAC
Encore® Latex Acclaim®	5795006	8.5	NA/LAC
Encore® Latex Acclaim®	5795007	9.0	NA/LAC
Encore® Latex Acclaim®	330100055	5.5	EMEA
Encore® Latex Acclaim®	330100060	6.0	EMEA
Encore® Latex Acclaim®	330100065	6.5	EMEA
Encore® Latex Acclaim®	330100070	7.0	EMEA
Encore® Latex Acclaim®	330100075	7.5	EMEA

Ansell Healthcare Europe NV/SA
—
Riverside Business Park – Block J
Boulevard International 55
1070 Brussels, Belgium

T. + 32 (0)2 528 74 00
F. + 32 (0)2 528 74 01
Email: info.europe@ansell.com
www.ansell.com

Product Name	Product Code	Size	Region(s)
Encore® Latex Acclaim®	330100080	8.0	EMEA
Encore® Latex Acclaim®	330100085	8.5	EMEA
Encore® Latex Acclaim®	330100090	9.0	EMEA
Gammex® Latex Standard	330085055	5.5	EMEA/APAC/ANZ
Gammex® Latex Standard	330085060	6.0	EMEA/APAC/ANZ
Gammex® Latex Standard	330085065	6.5	EMEA/APAC/ANZ
Gammex® Latex Standard	330085070	7.0	EMEA/APAC/ANZ
Gammex® Latex Standard	330085075	7.5	EMEA/APAC/ANZ
Gammex® Latex Standard	330085080	8.0	EMEA/APAC/ANZ
Gammex® Latex Standard	330085085	8.5	EMEA/APAC/ANZ
Gammex® Latex Standard	330085090	9.0	EMEA/APAC/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

Name: Samantha Marshall
Position: Director Regulatory Affairs Medical EMEA & APAC
Date: 02 March 2023
Place of Issue: Nuneaton, England
Revision: MED\MDR\ENCLAGAMLS\001