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 and risk of allergy to latex. This is a single-use device.

EMDN Code and Description: T01010201 - Polychloroprene Surgical Gloves

Basic UDI DI: 5414566 ENLGNLS340202 Y3

Product Name(s):

Product Name	Product Code	Size	Region(s)
Encore® Non-Latex	340111055	5.5	EMEA/ANZ
Encore® Non-Latex	340111060	6.0	EMEA/ANZ
Encore® Non-Latex	340111065	6.5	EMEA/ANZ
Encore® Non-Latex	340111070	7.0	EMEA/ANZ
Encore® Non-Latex	340111075	7.5	EMEA/ANZ
Encore® Non-Latex	340111080	8.0	EMEA/ANZ
Encore® Non-Latex	340111085	8.5	EMEA/ANZ
Encore® Non-Latex	340111090	9.0	EMEA/ANZ
Gammex® Non-Latex Sensitive	340007055	5.5	EMEA/APAC/ANZ
Gammex® Non-Latex Sensitive	340007060	6.0	EMEA/APAC/ANZ
Gammex® Non-Latex Sensitive	340007065	6.5	EMEA/APAC/ANZ
Gammex® Non-Latex Sensitive	340007070	7.0	EMEA/APAC/ANZ
Gammex® Non-Latex Sensitive	340007075	7.5	EMEA/APAC/ANZ
Gammex® Non-Latex Sensitive	340007080	8.0	EMEA/APAC/ANZ

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Product Name	Product Code	Size	Region(s)
Gammex® Non-Latex Sensitive	340007085	8.5	EMEA/APAC/ANZ
Gammex® Non-Latex Sensitive	340007090	9.0	EMEA/APAC/ANZ
Gammex® Non-Latex Sensitive	20277255	5.5	USA/CANADA
Gammex® Non-Latex Sensitive	20277260	6.0	USA/CANADA
Gammex® Non-Latex Sensitive	20277265	6.5	USA/CANADA
Gammex® Non-Latex Sensitive	20277270	7.0	USA/CANADA
Gammex® Non-Latex Sensitive	20277275	7.5	USA/CANADA
Gammex® Non-Latex Sensitive	20277280	8.0	USA/CANADA
Gammex® Non-Latex Sensitive	20277285	8.5	USA/CANADA
Gammex® Non-Latex Sensitive	20277290	9.0	USA/CANADA

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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BELGIUM

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