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: T01010203 Polyisoprene Surgical Gloves

Basic UDI DI: 5414566 GENLPIUG340206 3E

Product Name(s):

Product Name	Product Code	Size	Region(s)
GAMMEX® Non-Latex PI Underglove	340058055	5.5	EMEA/ANZ
GAMMEX® Non-Latex PI Underglove	340058060	6.0	EMEA/ANZ
GAMMEX® Non-Latex PI Underglove	340058065	6.5	EMEA/ANZ
GAMMEX® Non-Latex PI Underglove	340058070	7.0	EMEA/ANZ
GAMMEX® Non-Latex PI Underglove	340058075	7.5	EMEA/ANZ
GAMMEX® Non-Latex PI Underglove	340058080	8.0	EMEA/ANZ
GAMMEX® Non-Latex PI Underglove	340058085	8.5	EMEA/ANZ
GAMMEX® Non-Latex PI Underglove	340058090	9.0	EMEA/ANZ
GAMMEX® Non-Latex PI Underglove	20687255	5.5	NA
GAMMEX® Non-Latex PI Underglove	20687260	6.0	NA
GAMMEX® Non-Latex PI Underglove	20687265	6.5	NA
GAMMEX® Non-Latex PI Underglove	20687270	7.0	NA
GAMMEX® Non-Latex PI Underglove	20687275	7.5	NA
GAMMEX® Non-Latex PI Underglove	20687280	8.0	NA
GAMMEX® Non-Latex PI Underglove	20687285	8.5	NA

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Product Name	Product Code	Size	Region(s)
GAMMEX® Non-Latex PI Underglove	20687290	9.0	NA
ENCORE® Non-Latex PI Underglove	330114055	5.5	EMEA
ENCORE® Non-Latex PI Underglove	330114060	6.0	EMEA
ENCORE® Non-Latex PI Underglove	330114065	6.5	EMEA
ENCORE® Non-Latex PI Underglove	330114070	7.0	EMEA
ENCORE® Non-Latex PI Underglove	330114075	7.5	EMEA
ENCORE® Non-Latex PI Underglove	330114080	8.0	EMEA
ENCORE® Non-Latex PI Underglove	330114085	8.5	EMEA
ENCORE® Non-Latex PI Underglove	330114090	9.0	EMEA

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
Date: 05 January 2023
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