

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: T01010299 Synthetic Surgical Gloves – Other

Basic UDI DI: 5414566 GEPIHYB340 UL

Product Name(s):

Product Name	Product Code	Size	Region(s)
Encore® Non-Latex PI Hybrid	340105055	5.5	EMEA/ANZ
Encore® Non-Latex PI Hybrid	340105060	6.0	EMEA/ANZ
Encore® Non-Latex PI Hybrid	340105065	6.5	EMEA/ANZ
Encore® Non-Latex PI Hybrid	340105070	7.0	EMEA/ANZ
Encore® Non-Latex PI Hybrid	340105075	7.5	EMEA/ANZ
Encore® Non-Latex PI Hybrid	340105080	8.0	EMEA/ANZ
Encore® Non-Latex PI Hybrid	340105085	8.5	EMEA/ANZ
Encore® Non-Latex PI Hybrid	340105090	9.0	EMEA/ANZ
Gammex® PI Hybrid	340063055	5.5	EMEA/ANZ/NA
Gammex® PI Hybrid	340063060	6.0	EMEA/ANZ/NA
Gammex® PI Hybrid	340063065	6.5	EMEA/ANZ/NA
Gammex® PI Hybrid	340063070	7.0	EMEA/ANZ/NA
Gammex® PI Hybrid	340063075	7.5	EMEA/ANZ/NA
Gammex® PI Hybrid	340063080	8.0	EMEA/ANZ/NA
Gammex® PI Hybrid	340063085	8.5	EMEA/ANZ/NA
Gammex® PI Hybrid	340063090	9.0	EMEA/ANZ/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



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