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: T01010299 - Synthetic Surgical Gloves – Other

Basic UDI DI: 5414566 GPIHYBM3400 KR

Product Name(s):

Product Name	Product Code	Size	Region(s)
GAMMEX® PI Hybrid Micro	340002055	5.5	EMEA
GAMMEX® PI Hybrid Micro	340002060	6	EMEA
GAMMEX® PI Hybrid Micro	340002065	6.5	EMEA
GAMMEX® PI Hybrid Micro	340002070	7	EMEA
GAMMEX® PI Hybrid Micro	340002075	7.5	EMEA
GAMMEX® PI Hybrid Micro	340002080	8	EMEA
GAMMEX® PI Hybrid Micro	340002085	8.5	EMEA
GAMMEX® PI Hybrid Micro	340002090	9	EMEA

Conformity Assessment Procedure: Annex IX.

CE Certificate No: MDR 763361.

Certified through the British Standards Institution, Notified Body Number 2797.

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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
Date:	02 March 2023
Place of Issue:	Nuneaton, England
Revision:	MED\MDR\GAMPIHM\001