Ansell Healthcare Europe NV/SA
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EU DECLARATION OF CONFORMITY

Manufacturer Name/Address: Ansell Healthcare Europe NV/SA
Riverside Business Park,
Block J, Boulevard International 55,
1070 Brussels,
Belgium

SRN Number: BE-MF-000000691

Risk Class: Class I

Intended Purpose: A non-sterile medical device intended as an examination/treatment glove and a protective barrier when worn on the hands of healthcare providers, during patient examination, or for other sanitary purposes. The device is used mainly as a two-way barrier to protect both the patient and wearer against contaminants. This is a single-use device.

EMDN Code and Description: T01020299 – Synthetic Examination/Treatment Gloves - Other

Basic UDI-DI: 5414566 DAGP52S30EM20 RZ

Product Name(s):

Product Name	Size	Product Code	Market Regions
Ethiparat	S	M2080	EMEA
Ethiparat	M	M2079	EMEA
Ethiparat	L	M2078	EMEA
Dispos-A-Glove® (pair)	S	P52380	EMEA
Dispos-A-Glove® (pair)	M	P52370	EMEA
Dispos-A-Glove® (pair)	L	P52390	EMEA
Dispos-A-Glove® (single)	S	S3027	EMEA
Dispos-A-Glove® (single)	M	S3047	EMEA
Dispos-A-Glove® (single)	L	S3067	EMEA

Conformity Assessment Procedure: Annex I & Annex II + Annex III

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This EU Declaration of Conformity is issued under the sole responsibility of Ansell Healthcare Europe NV/SA.

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 Ansell Healthcare Europe NV

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 of issue: 02 March 2023
Place of issue: Nuneaton, England
Version No: MED\DAG_ETHIPNS\002