

## 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 & Description:** T01020299 - Synthetic Examination / Treatment Gloves – Other

**Basic UDI-DI:** 5414566 DAGP52S30EM20 RZ

**Product Name(s):**

| Product Name             | Size | Product Code | Market Region |
|--------------------------|------|--------------|---------------|
| 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

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 the Manufacturer



Ansell Healthcare Europe NV  
Riverside Business Park - Block J  
Bld Internationalelaan 55  
B-1070 Brussels  
BELGIUM

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