Ansell Healthcare Europe NV/SA
—
Riverside Business Park – Block J
Boulevard International 55
1070 Brussels, Belgium

T. + 32 (0)2 528 74 00
F. + 32 (0)2 528 74 01
Email: info.europe@ansell.com
www.ansell.com

# 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/SA
Riverside Business Park,
Block J, Boulevard International 55,
1070 Brussels,
Belgium

**SRN Number:** BE-MF-000000691

**Risk Class:** Class Is

**Intended Purpose:** A 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:** T01020201 – Vinyl Examination / Treatment Glove

**Basic UDI-DI:** 5414566 DAGMDGETHM33 W4

**Product Name(s):**

| Product Name | Code | Size | Region |
|---|---|---|---|
| Dispos-A-Glove® Sterile | MDG601 | S (single) | EMEA |
| Dispos-A-Glove® Sterile | MDG701 | M (single) | EMEA |
| Dispos-A-Glove® Sterile | MDG801 | L (single) | EMEA |
| | | | |
| Dispos-A-Glove® Sterile | MDG651 | S (pair) | EMEA |
| Dispos-A-Glove® Sterile | MDG751 | M (pair) | EMEA |
| Dispos-A-Glove® Sterile | MDG851 | L (pair) | EMEA |
| | | | |
| Ethiparat® Sterile | M3330 | S (pair) | EMEA |
| Ethiparat® Sterile | M3350 | M (pair) | EMEA |
| Ethiparat® Sterile | M3370 | L (pair) | EMEA |
| | | | |
| Ethiparat® Sterile | M3325 | S (single) | EMEA |

Ansell Healthcare Europe NV/SA
—
Riverside Business Park – Block J
Boulevard International 55
1070 Brussels, Belgium

T. + 32 (0)2 528 74 00
F. + 32 (0)2 528 74 01
Email: info.europe@ansell.com
www.ansell.com

| | | | |
|---|---|---|---|
| Ethiparat® Sterile | M3345 | M (single) | EMEA |
| Ethiparat® Sterile | M3365 | L (single) | EMEA |

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

For the sterility aspects of the device these are certified through the British Standards Institution, Notified Body Number 2797, Certificate MDR 763361 under Annex IX Chapters I & III.

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
Bld Internationalelaan 55
B-1070 Brussels
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\MDR\DAGETHS\001