Ansell Healthcare Europe NV/SA
—
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Boulevard International 55
1070 Brussels, Belgium

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DECLARATION OF CONFORMITY

This UK 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

UK Responsible Person: Ansell (U.K.) Limited
Building C,
Willerby Hill Business Park,
Willerby, Hull
HU10 6FE
United Kingdom

Risk Class: Class Is

GMDN Code & Definition: 59821 - Ethylene vinyl acetate examination/treatment glove, non-powdered

Product Name(s):

Product Name	Size	External Reference Code
DISPOS-A-GLOVE® Sterile	S (single) M (single) L (single) S (pair) M (pair) L (pair)	MDG601 MDG701 MDG801 MDG651 MDG751 MDG851
ETHIPARAT® Sterile	S (single) M (single) L (single) S (pair) M (pair) L (pair)	M3325 M3345 M3365 M3330 M3350 M3370

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Conformity Assessment Procedure: Part II – Annex VII

For the sterility aspects of the glove, these are certified through the British Standards Institution, Approved Body Number 0086, UKCA Certificate 762590, under Part II (Annex V).

We hereby declare that the medical device(s) specified above meet the provision of The Medical Devices Regulations 2002 (UK MDR 2002).

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
Date: 09 August 2023
Revision: MED\UKMDR\ETHYL_DAGETHIPSTER\002