

Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 concerning Personal Protective Equipment (PPE).

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE mark may be affixed. This declaration of conformity is issued under the sole responsibility of the manufacturer indicated below.

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|--|--|
| General Product Name: | Easimask |
| Legal Manufacturer: (Name on Label) | Full Support Healthcare Ltd, Harrowden Court, 66 - 80 Huxley Close, Park Farm Industrial Estate, Wellingborough, Northamptonshire, NN8 6AB, UK |
| Description | Particulate Respirators (filtering half masks) |
| Variants | As per Appendix II (This document) - Product Listing/Schedule |
| PPE Category | Category III |
| Intended Use | Filtering half masks to protect against particles |
| EU Authorised Representative: | Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta |

Conformity Assessment

The model(s) in Appendix II of this document are:

- in conformity with the provisions of the Personal Protective Equipment (PPE) Regulations (EU) 2016/425.
- identical to the PPE which is the subject of EU type-examination certificate of conformity No: CE 718536. BSI Netherlands B.V. (Notified Body No. 2797), Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands, performed the EU type-examination (Module B of PPE Regulation (EU) 2016/425) and issued the above certificate.
- subject to the conformity assessment procedures set out in Module D of PPE Regulation (EU) 2016/425 under surveillance of the notified body: BSI Netherlands B.V. (Notified Body No. 2797), Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands.

Declaration of Conformity

Full Support Healthcare declares, as the natural and legal person with sole responsibility for the manufacture, packaging and labelling, that the particulate respirator(s) listed on this certificate conform to the relevant provisions of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 concerning PPE in accordance with Annex 2 Essential Health & Safety requirements, Article 19 Conformity Assessment Procedure and Article 18 Risk categories of PPE registered Quality Management System, regardless of whether these operations are carried out by the manufacturer or on their behalf by a third party.

Authorisation

| | | | |
|---|----------|---------------------------|---------------------|
| Designated representative: | S. White | Position: | Commercial Director |
| Signature: | | Date: | 21.04.23 |
| Date effective from: | 21.04.23 | Date effective to: | 14.10.24 |
| <i>For and on behalf of Full-Support Healthcare Ltd</i> | | | |

Appendix I - Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

| Standard/Document Name | Description |
|------------------------|---|
| 2016/425 | Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 concerning PPE |
| EN 149:2001 +A1:2009 | Respiratory protective devices. Filtering half mask to protect against particles |

Appendix II - Product Listing/Schedule

The following products are covered by this Declaration of Conformity:

| Product Code | Product Description |
|--------------|--|
| FSM14 | FFP3 NR Valved Particulate Respirator – duckbill |
| FSM16 | FFP3 NR Particulate Respirator – duckbill |
| FSM17 | FFP3 NR D Valved Particulate Respirator – Custom-Fit |
| FSM18 | FFP3 NR D Particulate Respirator – Custom-Fit |

Appendix III - Version History

| Version | Compiled by | Date | Description |
|---------|-------------|----------|--|
| 1 | Ruth Roper | 24.05.21 | New formatted DoC with EU representative |
| 2 | Ruth Roper | 20.04.23 | Amendment to declaration of conformity section |