

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.

General Product Name:	Protective apron	
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	Protective apron with long sleeves and thumb loops, open-back gown, impervious	
Variants	As per Appendix II (this document) - Product Listing/Schedule	
PPE Category	Category I	
Intended Use	Designed for tasks where fully impervious non-sterile protection is needed, providing maximum protection and comfort.	
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.

Declaration of Conformity

Full Support Healthcare declares, as the natural and legal person with sole responsibility for the design, manufacture, packaging and labelling, that the protective apron(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, Article 18 Risk categories of PPE and BS EN ISO 13485 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 Stoute	Position:	CEO
Signature:		Date:	24.05.21	
For and on behalf of Full-Support Healthcare Ltd				



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	

Appendix II - Product Listing/Schedule The following products are covered by this Declaration of Conformity:

Product Code	Product Description	
20030	protective apron with long sleeves and thumb loops, open-back gown, impervious, universal size (5 x 20 boxes)	
28030	easilite blue protective apron long sleeves and thumb loops, open-back gown, impervious, universal size	
28030W easilite white protective apron long sleeves and thumb loops, open-back gown, impervious, universal size		

Appendix III - Version History

Version	Compiled by	Date	Description
1	Ruth Roper	24.05.21	New formatted DoC with EU representative