

# EU Type Examination Certificate

This is to certify that:

Summit Medical Inc.  
815 Vikings Pkwy, Ste 100  
St. Paul  
Minnesota  
55121  
USA

Holds Certificate Number:

CE 729741

In respect of:

**Model Guardian Face Shield CM-5001 Protective Eyewear  
To technical specification to Annex II (EHSR) of the PPE Regulation (EU) 2016/425  
PPE for use by healthcare professionals as per Commission recommendation 2020/403**

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Previous Notified Body: BSI 0086

First Issued: 2020-05-29

Latest Issue: 2020-05-29

Drs. Dave Hagenaaars, Managing Director

Effective Date: 2020-05-29

Expiry Date: 2021-05-29

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No. CE 729741

## Product Specification

**Product Name:** Face Shield

**Product Type:** Face protection for use by healthcare professionals

**Models:** Guardian Face Shield CM-5001-XXX  
Please note XXX relates to the packaging configuration

**Technical Specification:** Technical Specification to satisfy Annex II of the PPE Regulation (EU) 2016/425

**Product Description:** The eye and face protector listed on this certificate is for use by healthcare workers, first responders and other personnel involved in the efforts to contain the COVID-19 virus and avoid its further spread.

This face shield is made of 0.25 mm thick RPET film silicone coated, with a head band with width of 19 mm min.

The product covered by this certificate is not approved for industrial applications and the certificate is only valid as long as EU Commission recommendation sheet 2020/403 remains applicable.

**Product Assessments:** BSI 2020/403 Eye Protection Technical Specification

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## Certificate Administration Details

Technical File Reference: Technical File for Summit Medical Face Shield – CM-5001 ref 93938 Issue B

## Certificate Amendment Record:

Issue date	Comments	BSI Review No.
May 2020	First issue.	2797:20:3217669

## Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

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