

# EU Type Examination Certificate

This is to certify that:

Zhangjiagang Zhiyi Medical Health  
Products Co., Ltd  
Renmin Road, Leyu Town  
Zhangjiagang City  
Jiangsu  
215622  
China

Holds Certificate Number:

CE 727911

In respect of:

**Models ZY-MASK-01 and ZY-Mask-02 Filtering Face Masks  
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.**

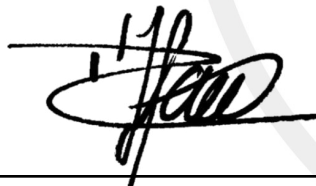
on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements 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: 2020-06-09

Latest Issue: 2020-06-09



Drs. Dave Hagenaaers, Managing Director

Effective Date: 2020-06-09

Expiry Date: 2021-06-09

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## Product Specification

**Product Name:** Particulate Filtering Respirator (Self-priming Filter Respirator).

**Product Type:** Filtering half masks for use by Healthcare professionals.

**Models:** ZY-MASK-01  
ZY-MASK-02.

**Technical Specification:** BSI 2020/403 filtering face mask technical specification.

**Classification:** FFP2 NR (both models).

**Product Descriptions:** The masks listed on this certificate are 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.

The ZY-MASK-01 is a vertical fold flat design of mask and the ZY-Mask-02 is a horizontal fold flat design of mask.

Both models are non-reusable respirators that are secured to the user by elasticated straps that are looped behind the ears.

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

**Product Assessments:** Products assessed against the requirements of BSI 2020/403 filtering face mask technical specification.

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## Certificate Administration Details

Technical File References:      Model ZY-MASK-01: ZY/CE-007, Edition A  
                                         Model ZY-MASK-02: ZY/CE-008, Edition A.

## Certificate Amendment Record:

| Issue date | Comments     | BSI Review No.  |
|------------|--------------|-----------------|
| June 2020  | First issue. | 2797:20:3175190 |

## 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.

The validity of the Certificate for the products is also dependent on the maintenance of the Conformity to Type Based on Internal Production Control Plus Supervised Product Checks at Random Intervals, Annex VII (Module C2), as referenced on BSI issued Certificate CE 727912.

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