

EU Type Examination Certificate

This is to certify that:

Zhende Medical Co., Ltd
Gaobu Town
Shaoxing
Zhejiang
312035
China

Holds Certificate Number:

CE 728114

In respect of:

**Model: N9501F Particulate Respirator.
To technical specification Annex II (EHSR) of the PPE Regulation (EU) 2016/425.
PPE for use by healthcare professionals as per Commission recommendation 2020/403.**

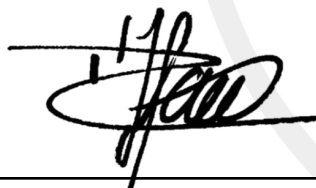
on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements 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: 2020-04-27

Latest Issue: 2020-04-27



Drs. Dave Hagenaaars, Managing Director

Effective Date: 2020-04-27

Expiry Date: 2021-04-27

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EU Type Examination Certificate

No. CE 728114

Product Specification

Product Name: Particulate Respirator.

Product Type: Particulate filtering half masks for use by Healthcare professionals.

Model: **N9501F.**

Classification: FFP2 NR un-valved.

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

Product Description: The respirator is non-reusable, secured to the face of the user by a pair of elasticated ear straps, and has no exhalation valve. The respirator is FFP2 class, vertical fold flat type.

The respirator 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.

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's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

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Certificate Administration Details

Technical File Reference: Zhende Medical Co., Ltd N9501F.

Certificate Amendment Record:

Issue date	Comments	BSI Review No.
April 2020	First issue.	2797:20:3201527

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 EU 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 728118.

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