EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number: CE 727499

In respect of:

Disposable Masks
To EN 149:2001 + A1:2009

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):

Drs. Dave Hagenaars, Managing Director

First Issued: 2021-04-14
Latest Issue: 2021-05-20

Effective Date: 2021-05-20
Expiry Date: 2026-04-14

PRODUCTS
RvA C 646

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BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A member of BSI Group of Companies.

EU Type Examination Certificate

No. CE 727499

Product Specification

Product Name:	Particulate Respirator.
Product Type:	Particulate filtering half masks.
Model:	**N9501F**
Classification:	FFP2 NR un-valved.
Technical Specification:	EN 149:2001 + A1:2009
Product Description:	The respirator is non-reusable, secured to the face of the user by a pair of elasticated ear straps, adjustable buckle, and has no exhalation valve. The respirator is FFP2 class, vertical fold flat type.

Product Specification

Product Name:	Particulate Respirator.
Product Type:	Particulate filtering half masks.
Model:	**N9501Z**
Classification:	FFP2 NR un-valved.
Technical Specification:	EN 149:2001 + A1:2009
Product Description:	The respirator is non-reusable, secured to the face of the user by a pair of elasticated head straps and has no exhalation valve. The respirator is FFP2 class, Horizontal fold flat type.

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Certificate Administration Details

Technical File Reference: : ZDYL/QSPPE-1, ZDYL/QSPPE-03

Certificate Amendment Record:

Issue date	Comments	BSI Review No.
April 2021	First issue.	2797:21:3171826
May 2021	Addition of Model N9501Z.	2797:21:3269512

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 727500.

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