EU Type Examination Certificate

This is to certify that:

Hunan Zhenheyikang Medical Instrument
Co., Ltd
No.6 Building Jingxiang Energy
No.55 Xiaguang east road
Gaoxin district
Xiangtan
Hunan
China

Holds Certificate Number: CE 758982

In respect of:

Respiratory protective devices to EN 149:2001+A1:2009
Filtering half masks to protect against particles
Model: ZK-10305 ~ FFP2 NR.

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: 2022-05-13
Latest Issue: 2022-05-13

Effective Date: 2022-05-13
Expiry Date: 2027-05-13

PRODUCTS
RvA C 646

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EU Type Examination Certificate

No. CE 758982

Product Specification

Product Type:	Respiratory protective device, filtering half masks to protect against particles.
Model:	ZK-10305.
Product Description:	The particulate respirator is a vertical fold flat style product designed to protect against solid and liquid particles. It is a single shift, non-valved, non-sterile product with a twin head band retention system incorporating adjustment buckles. The outer surface of the mask is coloured white and the head bands can be coloured white, yellow, blue, green, pink, black or red.
Technical Specification:	EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks top protect against particles.
EN 149 classification:	FFP2 NR.

Certificate Administration Details

Technical File Reference: Technical File for ZK-10305 Mask.

Certificate Administration Record and BSI internal Technical File Review reference

Issue date	Comments	BSI Project Ref.
May 2022	First issue.	2797:2022:3552843

Certificate validity

The Certificate holder is responsible for keeping the Notified Body advised of changes to any aspect of the overall process used 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.

Monitoring of manufactured PPE

The validity of the Certificate for the products is also dependent on the maintenance of the Conformity to Type Based on Quality Assurance of the Production Process, Annex VIII (Module D), as referenced on BSI issued Certificate CE 758983.

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