



GUO GUANG, ZUNHUA KAIGEER INDUSTRIAL CO., LTD

N95 MASK



SPECIFICATION

Product	Medical reusable N95 mask
Color	White
Dimensions	size 135x135mm,
Specification	50gsm PP non-woven surface fabric, 2layer x 25gsm melt blown fabric, 2layer x 35gsm PP
	iron nose clip 82x5mm,
	PP splash resistant material, ear loops 165x5mm
	DELTA P<49Pa/cm2
	P.F.E. 99%
FDA Certificate	Yes
CE Certificate	Yes
Manufacture Standard	GB19083-2010,
Package	5pcs/box, 200bags/carton, 1000pcs/carton, carton size: 77.5x47x36.5cm, GW: 9.6kg.
Price (USD/PC)	2.25
Lead Time	1,000,000 in stock and 500,000 pcs/day

医用N95口罩CE认证以及检测报告

Medical N95 mask CE certification and test report

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Report No. C20033103SR-01



Attestation of Conformity

No. ICR Polska/M6330399



Name and address of Registered Manufacturer: Zunhua Kaigeer Industrial Co., Ltd
North Second Ring West Road, Zunhua City, Hebei Province, China
Product name: N95 Medical masks
Product type/model: Ear hanging type
Trade mark: GUO GUANG

This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.

Relevant EC Directive: Medical Device Directive 93/42/EEC
Conformity assessment procedure: EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)
Classification: Class I according Rule 1 of Annex IX of Directive 93/42/EEC
Applied normative documents: EN 14683:2005
Applied Quality Management System: n/a

This AoC will remain valid only if Quality Management System Certificate remains valid. The assessment process has been carried out in accordance with the program PC-P-07-07. Evaluation has been carried out in accordance with test report made by: United Testing Technology (Hong Kong) Limited

No. of test report: C20033103SR-01
Issue date: 30.03.2020
Expiration date: 29.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3126.

This Attestation applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standard.



Director: Rafal Kalinowski

Warsaw, 30. 03. 2020.

ICR Polska Co. Ltd.

ul. Plac Przymierza 6, 03-944 Warszawa

www.icrpolska.com, e-mail: icrpolska@icrqa.com



TEST REPORT EN 14683

Medical face masks - Requirements and test methods

Report reference No.: C20033103SR-01
Tested by (+signature): Steven  see cover page
Approved by (+signature): Liuze  see cover page
Date of issue: Mar.,30, 2020



Testing laboratory

Name: United Testing Technology (Hong Kong) Limited
Address: Unit 04,7/F,Bright Way Tower,No.33 Mong Kok Road, Kowloon, HK.
Test location: (Same as above)

Client

Name: Zunhua Kaigeer Industrial Co., Ltd
Address: North Second Ring West Road, Zunhua City, Hebei Province, China

Test specification

Standard: EN 14683:2005
Test procedure: CE- MDD
Procedure deviation: N.A.
Non-standard test method: N.A.

Test Report Form No.: EN_14683

Test item

Description: N95 Medical masks
Model No.: Ear hanging type
Trade Mark: GUO GUANG
Manufacturer: Zunhua Kaigeer Industrial Co.,Ltd
Address: North Second Ring West Road, Zunhua City, Hebei Province, China
Classification: Type II

Certificate of Compliance



No. 0P200402R.ZCK0T20

Technical Construction File no. TCF-TPMJ2003313886-AG01

Certificate's
Holder:

Zunhua City Kai Ge Er Industrial Co., Ltd.
North Erhuan West Road, Zunhua, Tangshan
City, Hebei Province, China.

Certification ECM
Mark:



Product:

Mask

Model(s):

85mm*95mm, 175mm*95mm, 175mm*90mm,
170mm*90mm, 145mm*95mm,
145mm*85mm, 125mm*95mm, KN90
KN95, KN99, N95, FFP1, FFP2, FFP3

Verification to:

Standard:
EN 149:2001+A1:2009

related to CE Directive(s):
R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products according to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products, RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 02 April 2020

Expiry date: 01 April 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Badonni

Ente Certificazione Macchine Srl

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**Fiscal Year 2020
CERTIFICATION OF REGISTRATION**

This certifies that:

ZUNHUA KAIGEER INDUSTRIAL CO.,LTD

North Second Ring West Road, Zunhua City, HEBEI, 064200, CHINA

has completed the FDA Establishment Registration and Device Listing.

Owner/Operator Number: 10068134

Device Listing#: See annex



Registration Date: April 8, 2020
Expiration Date: December 31, 2020



**Fiscal Year 2020
CERTIFICATION OF REGISTRATION**

Annex to Device Listing# for Owner/Operator Number: 10068134

Listing No.	Code	Device Name	Proprietary Names	Activities
D387727	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance	Disposable masks Ear hanging type	Manufacturer Foreign Exporter
			Disposable medical masks Ear hanging type	
			Surgical masks Ear hanging type	
			Medical protective masks Ear hanging type	
			FFP1 masks Ear hanging type	
			FFP2 masks Ear hanging type	
D387734	MSH	Respirator, surgical	FFP3 masks Ear hanging type	Manufacturer Foreign Exporter
			N95 medical masks Ear hanging type	
			N95 protective masks Ear hanging type	
D387736	LRJ	Disinfectant, medical devices	KN95 masks Ear hanging type	Manufacturer Foreign Exporter
			Disinfectant Skin disinfectant	
			Sanitary wipes	
			Disinfectant liquid	

END OF THE ANNEX