

Product Name: N95 Daily Respirators Protective Mask (M001)

(Particle Filtration Efficiency $\geq 95\%$)

(Suitable for severe pollution PM2.5 concentration $<500 \mu\text{g}/\text{m}^3$)

Description:

Type:	NBGS-Respirator
Usage:	Wear it in sever fog and haze, automobile exhaust, kitchen, etc
Function:	Efficiently filters all kinds of particles in the air
Duration:	Mild pollution – 40 hours Moderate pollution – 32 hours Heavy pollution – 20 hours Severe pollution – 8 hours
Storage:	Store in a dry place with temperature at 0-30°C
Packing:	5pcs per box / 1,000 boxes per Carton (4kgs)
Shelf Life:	5 years

Product & Packing Photo:



Certification: ISO13485 / FDA / CE



**Fiscal Year 2020
CERTIFICATION OF REGISTRATION**

This certifies that:

**Wuxi Road Central Nursing New Energy/Economic&Technological Development Zone
Nangang City/HENAN,473003,CHINA**

has completed the FDA Establishment Registration for manufacturer and foreign export and Device Listing with the US Food & Drug Administration, through The Owner/ Operator Number for this Registration is: 10052114

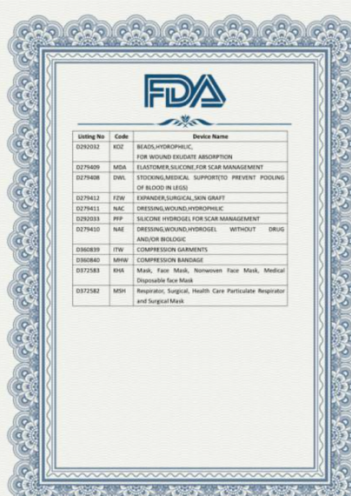
Device Listing #: See the attachment for the device listing No.

Almed will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Almed makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate holder's device or establishment by the US Food and Drug Administration.

Almed assumes no liability to any person or entity in connection with foregoing.

Date of verification: Nov 07, 2019
Date of expiration: Dec 31, 2020

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161400101 0217852 Rick Wang Phone:855-9403767676 info@almed.com
48801 00142 INC.
161401160 Almed, Sales & Engineering US USA 60611
161213 275 288 161213 275 288 info@almed.com



Listing No.	Code	Device Name
027402	K02	BEAD/HYDROPHILIC FOR WOUND EXUDATE ABSORPTION
027403	MDA	FLATSTERER SUTURE FOR SKIN MANAGEMENT
027404	DWL	STOOLING/MEDICAL SUPPORT/TO PREVENT FLOODING OF BLOOD IN UDD
027412	F2W	FERENCE SURGICAL SKIN GRAFT
027413	NAC	DRESSING/WOUND/HYDROPHILIC
029203	PPF	SALICONE HYDROGEL FOR SKIN MANAGEMENT
027410	NAC	DRESSING/WOUND/HYDROGEL WITHOUT DRUG AND/OR BIOLOGIC
026808	ITW	COMPRESSION GARMENTS
026840	MMW	COMPRESSION GARMENTS
027281	EM4	Mask, Face Mask, Nonwoven Face Mask, Medical Disposable Face Mask
027282	MSH	Respirator, Surgical, Health Care Particulate Respirator and Surgical Mask

Verification of Conformity
Certificate No.: HB-20200313-01

This is to certify that during the examination of the Technical Documentation provided by the manufacturer:

Name: [REDACTED]
Address: [REDACTED]

On its product as follows:


Product Name: Disposable mask, M95 respiratory protective mask
Type/Model/Spec. / Classification: Class I

No Non-compliance according to the requirements of the Medical Device Regulation (EU) 2017/745 Annex B and Annex 10 was detected, and the aforementioned device complies with the Regulation including all General Safety and Performance Requirements defined in Annex I.

The manufacturer has provided the EU Declaration of Conformity according to the Medical Device Regulation (EU) 2017/745 - article 19 requirements, confirming that this medical device, as stipulated above, is fulfilling the applicable requirements of the Medical Device Regulation (EU) 2017/745.

Issue Date: Mar. 13, 2020
Date of expiry: Mar. 12, 2025

Justo

CE  

ALMED SERVICE INC.
Room 606, No. 138 Shuangfeng Rd., Pudong, 200120 Shanghai, China
E-mail: info@almed.com.cn

EC Certificate
Production Quality Assurance System

Manufacturer: **Henan Public Medical CO., LTD.**
Wuxi Road Central Nursing New Energy/Economic&Technological Development Zone
Nangang City/HENAN,473003,CHINA

EC-Representative: **KINGWELAD SERVICE LIMITED**
161213 275 288

Product Category(s): **Medical Device for Dressing
Medical Device Dressing
Surgical Mask, Face Mask, Nonwoven Face Mask, Medical Disposable Face Mask
Respirator, Surgical, Health Care Particulate Respirator and Surgical Mask**

Report No.: 0217852
Issue Date: 2019-11-07
Valid Until: 2020-12-31

Page 1 of 1

EC Certificate
Production Quality Assurance System

Manufacturer: **Henan Public Medical CO., LTD.**
Wuxi Road Central Nursing New Energy/Economic&Technological Development Zone
Nangang City/HENAN,473003,CHINA

Facility(s): **Henan Public Medical CO., LTD.
Wuxi Road Central Nursing New Energy/Economic&Technological Development Zone
Nangang City/HENAN,473003,CHINA**

Product Category(s): **Medical Device for Dressing
Medical Device Dressing
Surgical Mask, Face Mask, Nonwoven Face Mask, Medical Disposable Face Mask
Respirator, Surgical, Health Care Particulate Respirator and Surgical Mask**

Report No.: 0217852
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Page 1 of 1

CERTIFICATE
No. Q14 18 11 8488 893

Holder of Certificate: **Henan Public Medical CO., LTD.**
Wuxi Road Central Nursing New Energy/Economic&Technological Development Zone
Nangang City/HENAN,473003,CHINA

Facility(s): **Henan Public Medical CO., LTD.
Wuxi Road Central Nursing New Energy/Economic&Technological Development Zone
Nangang City/HENAN,473003,CHINA**

Certification Work: **Medical Device for Dressing
Medical Device Dressing
Surgical Mask, Face Mask, Nonwoven Face Mask, Medical Disposable Face Mask
Respirator, Surgical, Health Care Particulate Respirator and Surgical Mask**

Applied Standard(s): **ISO 13485:2015**

Report No.: 0217852
Issue Date: 2019-11-07
Valid Until: 2020-12-31

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**Fiscal Year 2017
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Device Listing #: See the attachment for the device listing No.

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