

CE 符合性声明

CE Declaration of Conformity

EC Declaration of Conformity

Manufacturer:

Hunan Ziranyun Biological Engineering Co., Ltd
Address: No.88 Dengta Road, Qiyang Economic
Development Zone, Qiyang County,
Yongzhou City, Hunan Province, China. 426100

whose single Authorized EU-Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMID: DE/0000047791
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

*Disposable Medical Mask (No Sterile);
Models: ZRYWMKZ-0003
ZRYWMKZ-0004*

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

Hunan Ziranyun Biological Engineering Co., Ltd
Address: No.88 Dengta Road, Qiyang Economic Development Zone, Qiyang County,
Yongzhou City, Hunan Province, China. 426100

Yongzhou April 10, 2020
Place, date

Lin Sun Quality Manager
Legally binding signature, Function

FDA 注册信息

FDA Registration Information



The 3rd Party Document of Medical Device Registration

Note:

This file is Not being issued by FDA. We, GTS, as the 3rd party, produce it, intended to facilitate customer display & transmit information. The following contents, FDA registered Facility/Owner/Operator&FDA listing Medical Device, are excerpted from database at www.fda.gov.

Establishment:

[Hunan Ziranyun Biological Engineering Co., Ltd](#)

No.88 Dengta Road, Qiyang Economic Development Zone, Qiyang County ,
Yongzhou, Hunan, CHINA 456833

Registration Number / FEI Number*:

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Status: **Active**

Date of Registration Status: **2020**

Owner/Operator

[Hunan Ziranyun Biological Engineering Co., Ltd](#)

No.88 Dengta Road, Qiyang Economic Development Zone, Qiyang County ,
Yongzhou, Hunan, CHINA 456833

Owner/Operator Number: [10071292](#)

Official Correspondent

Contact Name: Xuhao Zhang International Trade Manager

No.88 Dengta Road, Qiyang Economic Development Zone, Qiyang County ,
Yongzhou, Hunan, CHINA 456833

Tel: +86-199-67626996 E-mail: owen.zhang@ziranyun.com

Devices Listing Information

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
Disposable Medical Protective Mask	LYU	1	D39****	Manufacturer
Disposable Medical Mask	LYU	1	D39****	Manufacturer
KN95 Disposable Medical Mask	MSH	2	D39****	Manufacturer

Please careful protect your Listing Number.

FDA

Signature: 

Professional FDA Registration Services, by Shanghai Global Testing Services Co., Ltd.
More details on the website: <http://www.gts-lab.com>
Need help? Contact us, GTS, at +86(021) 33637866 & info@gts-lab.com
FDA CERTIFICATE NUM: GTS24291