

CE 欧代注册信息

CE EAR Registration Info



Registration Notification

Reference number: JH-ERA-20742V00

Issued date: June 12, 2020

This certificate will be automatically void if the Notification is rejected by the EU Authorities or upon termination of the EAR.

This is certify that, According to Medical Device 93/42/EEC(MDD), we accepts the appointment to be the Authorized European Representative for products which listed in the attached agreement between below manufacturer and Luxus Lebenswelt GmbH.

Manufacturer: Hunan Ziranyun Biological Engineering Co., Ltd

Address: No.88 Dengta Road,Qiyang Economic Development Zone,
Qiyang County,Yongzhou City, Hunan Province,China. 426100

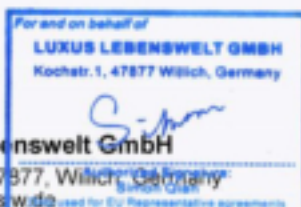
The Manufacturer declares that the Medical device complies with de Directive including all essential requirements.

According to Medical Device 93/42/EEC(MDD), the European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011, the German Competent Authority is notified of the manufacturer's Medical Devices and has allocated registration numbers shown in:

Disposable Medical Mask (No Sterile)

Registration number: DE/CA20/01-Luxuslebenwelt-442/20

Where the manufacturer affix the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) and standards have and continue to be met.



Luxus Lebenswelt GmbH

Kochstr. 1, 47877, Willich, Germany
info.m@luxuswelt.de

检测结果 (Test Results)

No. BOL3VF2T124847L1

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样品名称 (Sample Description)	一次性使用医用口罩 (非无菌) Disposable Medical Mask(No Sterile)	样品规格 (Sample Specification)	规格 Specification: 17.5cm*9.5cm 型号 Model: ZRYWVKZ-0003
委托单位 (Applicant)	湖南自然韵生物工程股份有限公司 HUNAN ZIRANYUN BIOLOGICAL ENGINEERING CO.,LTD	商标 (Trade Mark)	——
到样日期 (Received Date)	2020-06-08	生产日期或批号 (Manufacturing Date or Lot No.)	生产日期 Manufacturing Date: 2020 年 05 月 16 日 生产批号 Manufacturing Lot No.: 20200516
检测日期 (Test Date)	2020-06-08~2020-06-17	样品等级 (Sample Grade)	——
样品数量 (Sample Quantity)	80pcs	检测类别 (Test Type)	委托检测 (Commissioning Test)
样品状态 (Sample Status)	正常 Normal	检测环境 (Test Environment)	符合要求 (To meet the requirements)
检测项目 (Test Items)	见下页 See the next page		
检测方法 (Test Methods)	见下页 See the next page		
所用主要仪器 (Main Instruments)	电热恒温培养箱 Electric Heating Constant Temperature Incubator、细菌过滤效率检测仪 Bacterial filtration efficiency detector 等 etc.		
备注 (Note)	限值标准 Limit Standard: EN 14683: 2019 受检单位 Inspection: 湖南自然韵生物工程股份有限公司 HUNAN ZIRANYUN BIOLOGICAL ENGINEERING CO.,LTD 以上样品信息由委托单位提供 The information of above sample was provided by the applicant.		
	编制人 (Edited by)	朱萍	
	审核人 (Checked by)	郭惠	
	批准人 (Approved by)	戴晴	
	签发日期 (Issued Date)	2020-06-17	



☎ Hotline 400-819-5688
www.ponytest.com

谱尼测试集团上海有限公司

公司地址: 上海市松江区文翔东路 99 号 7 幢 2 层

检测地址: 上海市松江区文翔东路 99 号 5 幢、6 幢、7 幢 1 层、7 幢 3 层

上海市徐汇区桂平路 680 号 35 幢 2-4 楼、6 楼

电话: 021-37895599

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

CE 符合性声明

CE Declaration of Conformity

EC Declaration of Conformity

Manufacturer:

whose single Authorized EU-Representative:

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

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: ZRYYWKZ-0003
ZRYYWKZ-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