WORK®

HANGZHOU SHANYOU MEDICAL EQUIPMENT CO., LTD.

Professional Medical Manufacturer

Top Quality Product

Raw Material Control

Customer Service Support

Strict Production Process

Manufacturer: HANGZHOU SHANYOU MEDICAL EQUIPMENT CO., LTD.
Address: No. 138, Louta Development Zone, Guancun Village, Louta Town, Xiaoshan District, Hangzhou, 311266, Zhejiang, China.
Email: sale@symedi.com Tel: 86-571-82304593 Fax: 86-571-82305195

Company Profile

公司简介

杭州山友医疗器械有限公司

Hangzhou Shanyou Medical Equipment Co., Ltd.

杭州山友医疗器械有限公司成立于 2002 年，一直从事麻醉呼吸耗材的生产，产品通过 CE，ISO，FDA 等认证，远销德国，美国，日本等五十几个国家，广受国外用户的好评。绝大多数产品为二类灭菌产品，数量大，要求高。经过 18 年的不断发展壮大，目前建筑总面积为 68000 平方米，净化车间达 15000 平方米。

因疫情需要，2020 年 2 月初开始筹备医用口罩的生产。医用外科口罩和一次性医用口罩（ EN 14683-2019 ）已经取得 **CE 认证和美国 FDA 列示**，以及国内医用外科口罩（ YY 0469-2011 ）的注册证和一次性使用医用口罩（ YY/T0969-2013 ）的注册证。我司购买了九条最新的高速自动化口罩生产线，以及上百条常规口罩生产线，**日产能可达 800 万只**，目前产品大量出口到英国、德国、法国、西班牙等国，政府标单为主。此外，公司采购了近 200 条 KN95/FFP2 立体口罩生产线，**日产能 400 万只**。以上产品均获得了医保商会白名单。我司口罩严格按照国际标准生产，从采购、生产、质检、包装运输各个环节层层把关，保证出厂的每只口罩符合规范和客户要求。

Established in 2002, Hangzhou Shanyou Medical Equipment Co., Ltd. has been manufacturing anesthesia and respiratory disposable products. Certified with CE, ISO and FDA, our company enjoys very good reputation among our customers from more than 50 countries such as Germany, USA and Japan, etc. Current building area is 68,000 square meters while the clean room workshop is 15,000 square meters.

The production lines of Medical Masks were introduced in February 2020 due to the outbreak of coronavirus epidemic. Since we have plenty of experiences in medical devices production, we got everything ready within one month. Now we've completed registration of **Surgical Face Mask (type IIR)** and **Medical Face Mask (type I, type II)** according to **EN 14683-2019**. The capacity for medical face masks is **8 million pcs/day**, that's 240 million per month. We've been exporting to UK, France, Spain, Germany, mostly government tenders in huge quantities. Meanwhile, we've already purchased about 200 production lines on KN95 (**FFP2**) masks, started mass production on May 8th, estimated capacity is about **4 million pcs/day**. Our FFP2 mask obtained the CE certificate notified by Universal Certification. Also this mask fulfilled Dekra testing of corona sars-cov-2.

We strictly follow international rules to manufacture our products, make sure each item meet specific regulations and customer requirements.

Manufacturer: HANGZHOU SHANYOU MEDICAL EQUIPMENT CO., LTD.
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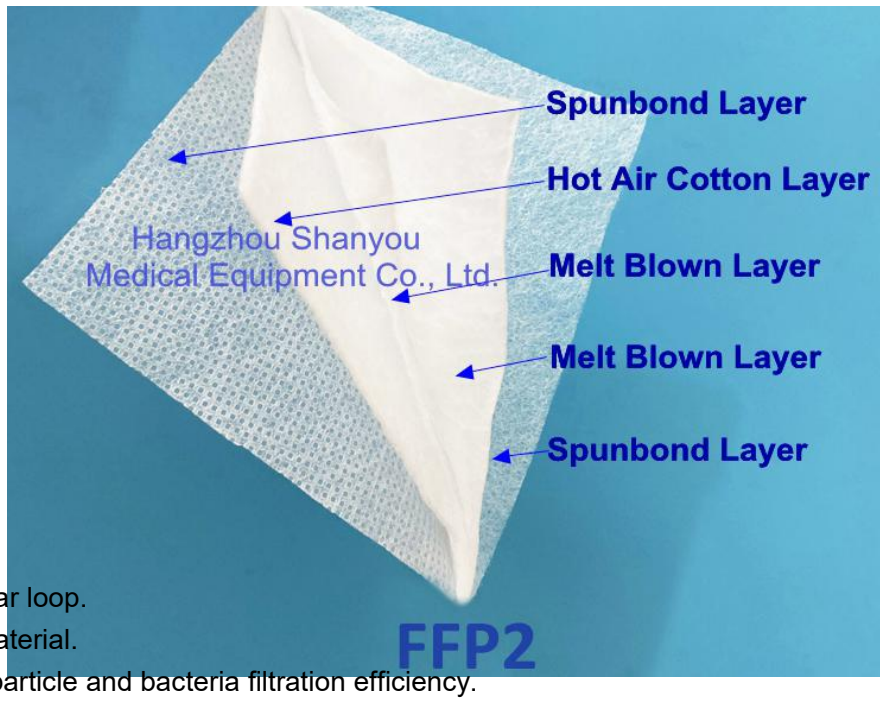
Email: sale@symedi.com Tel: 86-571-82304593 Fax: 86-571-82305195

Conform to EN 149:2001+A1:2009 Standard

Product	REF/Type	Sterilization	Package
FFP2 Mask	SY95-1	**Non-sterile**	1pcs/bag, 10bags/box, 50boxes/CTN, 68.5*37*34.5cm 7/5kgs
FFP2 Mask	SY95-1	**Non-sterile**	1pcs/bag, 10bags/middle bag, 80bags/CTN,64*41*50cm 9.6/8.2kgs



FEATURES :

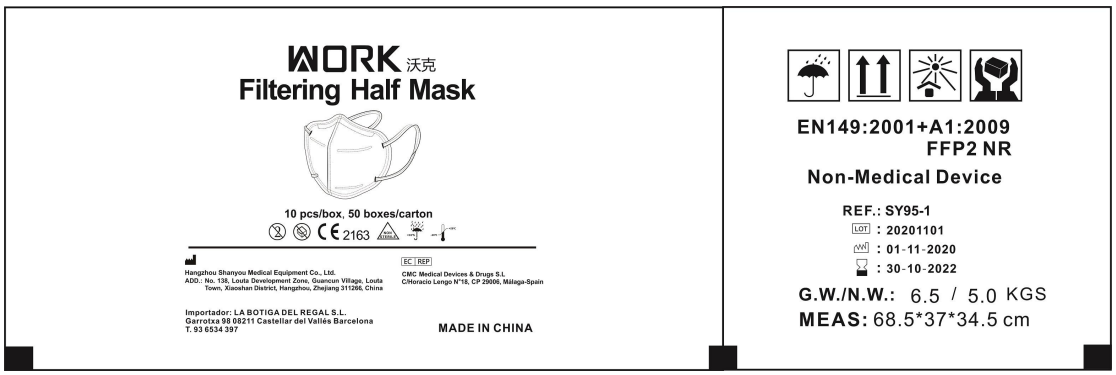
- Single use.
- Foldable design.
- Adjustable nose clip, elastic ear loop.
- Non-toxic and non-irritating material.
- 4 or 5 layers protection: high particle and bacteria filtration efficiency.
- Prevent bacteria, dust, pollen, airborne chemical particulate, smoke and mist.

Artwork of FFP2 Filtering Half Mask:

1pcs/bag

10pcs/box

50boxes/CTN, 500pcs/CTN

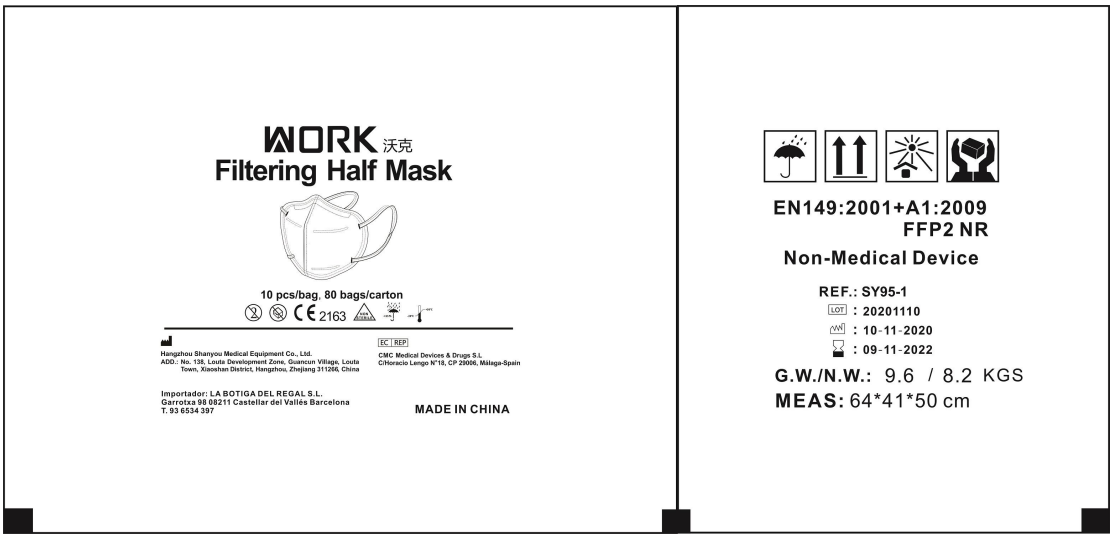


Package Image of FFP2 Filtering Half Mask:

1PCS/bag

10PCS/middle bag

80bags/CTN, 800pcs/CTN



CE Certificate for FFP2 Filtering Half Mask

CE 证 – FFP2 口罩

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate Nr: 2163-PPE-635/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

HANGZHOU SHANYOU MEDICAL EQUIPMENT CO. LTD.

at the following manufacturing site

No. 138, Louta Development Zone, Guancun Village, Louta Town, Xiaoshan District, Hangzhou, 311266, Zhejiang, CHINA

Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation. The details of compliance is given in technical report numbered 2163-PPE-636/01

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial Nr.	Date	Issuing NB Nr.
SY95-1	FFP2	2163-PPE-635	28/04/2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **28/04/2020** and will be valid for one year, until **27/04/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

The validity of this certificate can be verified online.

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
UNIVERSALCERT.COM

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate Nr: 2163-PPE-635

Respiratory protective devices, filtering half masks to protect against particles manufactured by

HANGZHOU SHANYOU MEDICAL EQUIPMENT CO. LTD.

No. 138, Louta Development Zone, Guancun Village, Louta Town, Xiaoshan District, Hangzhou, 311266, Zhejiang, CHINA

are tested and evaluated according to

EN 149:2001+A1:2009 Respiratory Protective Devices - Filtering Half Masks To Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation. The details of essential requirement compliance is given in technical report numbered 2163-PPE-636.

Product Definition

Brand Name: WORK 沃克 **Model:** SY95-1

Filtering half mask
Total Inwards Leakage: Class – FFP2

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **28/04/2020** and will be valid for 5 years if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

The validity of this certificate can be verified online.

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
UNIVERSALCERT.COM

EC Declaration of Conformity of FFP2 Filtering Half Mask

CE 符合性声明 – FFP2 口罩

Hangzhou Shanyou Medical Equipment Co., Ltd.	Documentation No.	TCF.01 Appendix 1
	Declaration of Conformity	EU 2016/425
Filtering Half Mask, EN149:2001+A1:2009, FFP2 NR	Date: 28/10/2020	Rev. A/1

EU DECLARATION OF CONFORMITY

Name and address of the Manufacturer: **Hangzhou Shanyou Medical Equipment Co., Ltd.**
No. 138, Louta Development Zone, Guancun Village, Louta Town, Xiaoshan District, Hangzhou, 311266, Zhejiang, China

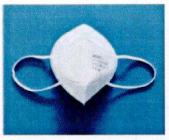
Name and address of the European Authorized Representative: **CMC Medical Devices & Drugs S.L**
C/Horacio Lengo Nº 18, CP 29006, Málaga-Spain

This declaration of conformity is issued under the sole responsibility of the manufacturer.

The manufacturer declares that the PPE products described hereafter:

Product Name: **Filtering Half Mask**

Product Photograph:



Type/Class: **FFP2 NR**
Model/REF.: **SY95-1**
Certificate Serial Nr.: **2163-PPE-635**

is in conformance with the provisions of **Annex V (Module B)** and **Annex VII (Module C2)** of the **Personal Protective Equipment Regulation (EU) 2016/425**.

The filtering half mask SY95-1 meets the requirements of the harmonized standard **EN 149:2001 + A1:2009** used to confirm the conformity with REGULATION (EU) 2016/425 on personal protective equipment.

Notified Body: **Universal Certification and Surveillance Service Trade Ltd. Co.**
Necip Fazıl Bulvarı, Keyap Sitesi, E2 Blok No: 44/84 Yukarı Dudullu, Ümraniye-Istanbul

Notified Body Nr.: **2163**

The notified body Universal Certification and Surveillance Service Trade Ltd. Co. (Nr. 2163) performed the EU type-examination (Module B) and issued the EU type-examination certificate number 2163-PPE-635.

The filtering half mask SY95-1 is subject to the conformity of assessment procedure Module C2 with certificate number 2163-PPE-635/01 under surveillance of the notified body Universal Certification and Surveillance Service Trade Ltd. Co. (Nr. 2163).

Declaration of Conformity is valid until: 27/05/2025

Hangzhou, 28/10/2020
Place and date

余百明 (Baiming Yu) / General Manager
Name and function

Page 1 of 1

Test Report of FFP2 Filtering Half Mask (DEKRA)

检验报告 – FFP2 口罩 (德凯)

Bewertung der Konformität von Corona SARS-Cov-2 Pandemie Atemschutz (CPA) nach dem Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken Revision 1

Evaluation of the conformity of corona sars-cov-2 pandemic respiratory protection (CPA) according to the testing principle for corona sars-cov-2 pandemic respiratory protection masks revision 1

Berichtsnummer *Report number*	3417278.10-CPA Revision 1
Prüfgegenstand *Test subject*	Corona SARS-CoV-2 Atemschutzmaske *Corona SARS-CoV-2 respiratory protective mask*
Modell *Type*	WORK Filtering Face Mask
Hersteller *Manufacturer*	Hangzhou Shanyou Medical Equipment Co., Ltd. No. 138, Louta Development Zone, Guancun Village, Louta Town, Xiaoshan District, Hangzhou, Zhejiang 311266, China
Importeur *Importer*	Hangzhou Shanyou Medical Equipment Co. Ltd. No. 138, Louta Development Zone, Guancun Village, Louta Town, Xiaoshan District Hangzhou, Zhejiang 31 1 266

Die Anforderungen des Prüfgrundsatzes sind *The requirements of the test principle are*	✓ Erfüllt *Fulfilled*

Die technische Wirksamkeit des oben genannten Produkts ist im Rahmen der Empfehlung (EU) 2020/403 der Europäischen Kommission vom 13. März 2020 über Konformitätsbewertungs- und Marktüberwachungsverfahren im Kontext der COVID-19 Bedrohung zu vermuten.
The technical efficiency of the above-mentioned product is to be presumed within the framework of the European Commission Recommendation (EU) 2020/403 of 13th March 2020 on conformity assessments and market surveillance procedures in the context of the COVID-19 risk.

Der Prüfgrundsatz kann unter dem folgenden Link eingesehen werden:
The test principle can be accessed under the following link:
http://www.zls-muenchen.de/aktuell/index.html

Diese Bewertung ist gültig vom 24.04.2020 bis 24.04.2021.
This evaluation of conformity is valid from 2020-04-24 until 2021-04-24.

DEKRA Testing and Certification GmbH
Bochum, 18.06.2020

Jörg-Timm Kilisch
Geschäftsführer *Managing Director*

DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart
Zertifizierungsstelle: Dinnendahlstraße 9, 44809 Bochum,
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.com

DEKRA

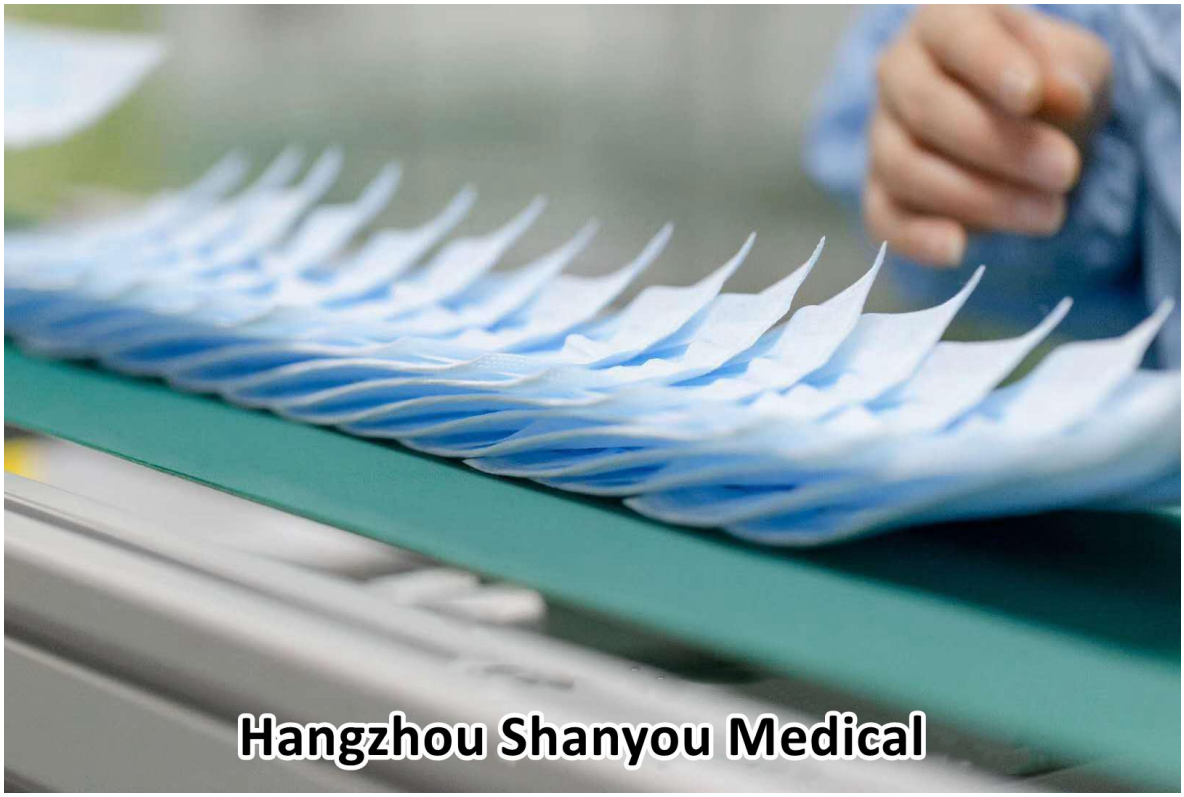
Mask type WORK

DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart
Zertifizierungsstelle: Dinnendahlstraße 9, 44809 Bochum,
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.com

Workshop (Clean Room) Photo 净化车间照片


Hangzhou Shanyou Medical


WORK
Hangzhou Shanyou Medical


Hangzhou Shanyou Medical


Hangzhou Shanyou Medical

Factory Overview 工厂概览


Hangzhou Shanyou Medical


Hangzhou Shanyou Medical

Business License

营业执照

统一社会信用代码
91330109738424 58XP (1/1)

营业执照

(副 本)

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息

名　　称	杭州山友医疗器械有限公司	注册资本	伍佰万元整
类　　型	有限责任公司（自然人投资或控股）	成立日期	2002 年 04 月 29 日
法定代表人	余百明	营业期限	2002 年 04 月 29 日 至 长期
经营范围	生产：第Ⅰ类 6866-3-病人防护用品，第二类 6809 泌尿肛肠外科手术器械，第二类 6821 医用电子仪器及设备，第二类 6822 医用光学器具、仪器及内窥镜设备，第二类 6854 手术室、急救室、诊疗室设备及器具，第二类 6866 医用高分子材料及制品；02 无源手术器械，07 医用诊察和监护器械，08 呼吸、麻醉和急救器械，14 注输、护理和防护器械； 生产：消毒剂、卫生用品（依法须经批准的项目，经相关部门批准后方可开展经营活动）	住　　所	浙江省杭州市萧山区楼塔镇管村村楼塔开发区 138 号

登记机关　杭州市萧山区市场监督管理局

2019 年 07 月 19 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn　　市场主体应当于每年 1 月 1 日至 6 月 30 日通过国家信用公示系统报送公示年度报告。　　国家市场监督管理总局监制

Production Permission License

医疗器械生产许可证

医疗器械生产许可证

许可证编号：浙食药监械生产许 20130022 号

企业名称：	杭州山友医疗器械有限公司	生产地址：	浙江省杭州市萧山区楼塔镇管村村楼塔开发区 138 号
法定代表人：	余百明	生产范围：	旧版：第二类 6809 泌尿肛肠外科手术器械，6821 医用电子仪器设备，6822 医用光学器具、仪器及内窥镜设备，6854 手术室、急救室、诊疗室设备及器具，6866 医用高分子材料及制品；新版：第二类 08-05-呼吸、麻醉、急救设备辅助装置，08-06-呼吸、麻醉用管路、面罩，14-04-止血器具，14-05-非血管内导（插）管，14-13-手术室感染控制用品，14-14-医护人员防护用品***
企业负责人：	余百明		
住　　所：	浙江省杭州市萧山区楼塔镇管村村楼塔开发区 138 号	发证部门：	浙江省药品监督管理局
有效期限：至	2022 年 11 月 22 日	发证日期：	2020 年 3 月 日

国家食品药品监督管理总局制

CE Certificate
杭州山友 CE 证书

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60151185 0001

Report No.: 15049271 019

Manufacturer:
Hangzhou Shanyou Medical Equipment
Co., Ltd.
No. 138,Louta Development Zone
Guancun Village,Louta Town
Xiaoshan District
Hangzhou
311266 Zhejiang
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60147797 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-08-07

Date: 2020-08-07

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1 Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60151185 0001
Report No.: 15049271 019

Manufacturer:
Hangzhou Shanyou Medical Equipment Co., Ltd.
No. 138,Louta Development Zone
Guancun Village,Louta Town
Xiaoshan District
Hangzhou
311266 Zhejiang
P.R. China

Products:
- Endotracheal Tubes
- Laryngeal Mask Airways
- Laryngoscope Blades
- Face Masks
  (Oxygen Mask, Non-rebreathing Mask, Nebulizer Mask)
- Suction Catheters
- Nasal Oxygen Cannulas
- Disposable Breathing Circuits
- Yankauer Suction Sets
- Anesthesia Masks
- Filters/HMEF
- Catheter Mounts
- Nasogastric Tubes

Aspects of manufacture concerned with securing and maintaining sterile conditions only:
- Endotracheal Tube Holders
- Artery Compression Tourniquets
- Intubating Stylets
- Guedel Airways
- Medical Face Masks

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-08-07

Fuxiu Sheng

ISO 13485 Certificate
杭州山友 ISO 13485 证书

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Hangzhou Shanyou Medical Equipment Co., Ltd.
No. 138,Louta Development Zone
Guancun Village,Louta Town
Xiaoshan District
Hangzhou
311266 Zhejiang
P.R. China

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-07-31
Certificate Registration No.:	SX 60151059 0001
An audit was performed. Report No.:	15049271 017
This Certificate is valid until:	2023-04-17

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Date 2020-07-31

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1 Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60151059 0001
Report No.: 15049271 017

Organization:
Hangzhou Shanyou Medical Equipment Co., Ltd.
No. 138,Louta Development Zone
Guancun Village,Louta Town
Xiaoshan District
Hangzhou
311266 Zhejiang
P.R. China

Scope:
Design and Development, Manufacture and Distribution of Disposable Breathing Circuits;
Manufacture and Distribution of Endotracheal Tubes, Laryngeal Mask Airways, Laryngoscope Blades, Face Masks (Oxygen Mask, Non-rebreathing Mask, Nebulizer Mask), Suction Catheters, Nasal Oxygen Cannulas, Endotracheal Tube Holders, Artery Compression Tourniquets, Intubating Stylets, Guedel Airways, Yankauer Suction Sets, Anesthesia Masks, Filters/HMEF, Catheter Mounts, Nasogastric Tubes, Medical Face Masks

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Date: 2020-07-31

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle