

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
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: 2018-07-19
Certificate Registration No.: SX 60128360 0001
An audit was performed. Report No.: 15049271 010
This Certificate is valid until: 2020-04-17

Certification Body



Date 2018-07-19



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 696-1371 Fax: +49 221 696-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60129357 0001
Report No.: 15049271 010

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

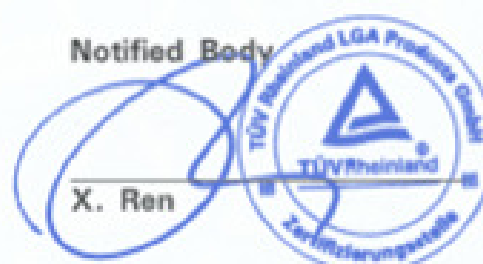
Products:

- 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

Date: 2018-07-19



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

Registration No.: DD 60129357 0001

Report No.: 15049271 010

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

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60118922 0001

Expiry Date: 2022-04-17

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: 2018-07-19

截图(Alt + A)

Date: 2018-07-19

Notified Body



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.

Hangzhou Shanyou Medical Equipment Co., Ltd.

Documentation no. SY-CE-19- 11.1

Declaration of Conformity MDR

Medical Face Masks, Type I

Date: 2020-03-12

Rev. A/0

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY

Name und Adresse des Herstellers: /
Name and address of the manufacturer:

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

Bevollmächtigter der EG: /
EC Authorized Representative:

Llins Service & Consulting GmbH
Obere Seegasse 34/2, 68124 Heidelberg, Germany

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that

das Medizinprodukt: /
the medical device:

Medizinische Gesichtsmasken / Medical Face mask
Modell/ Model: FMA, FMB, FMC, FMD

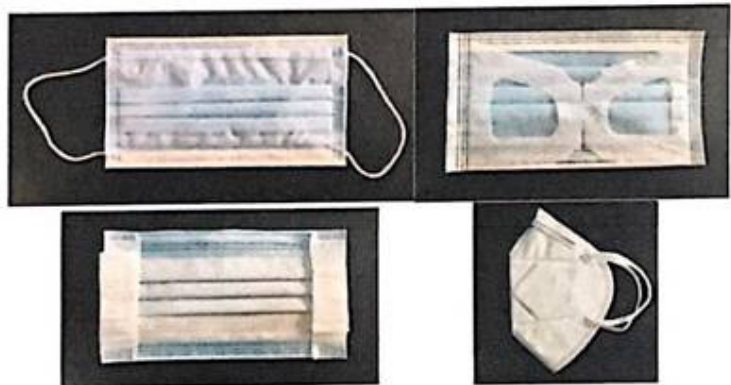
UMDNS-Code: / UMDNS code:

12447

Grundlegende UDI-DI: / Basic UDI-DI:

/

Produktfotografie: / Product photograph:



der Klasse: / of class:

I

nach Anhang VIII der Verordnung EU 2017/745 (MDR) / according to Annex VIII of Regulation (EU) 2017/745

Erfüllt die Bestimmungen der Verordnung EU 2017/745 (MDR). Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. / meets the provisions of the Regulation (EU) 2017/745 which apply to it. The declaration of conformity is valid in connection with the batch-related "final inspection report" of the device.

Konformitätsbewertungsverfahren:
Conformity assessment procedure:

EU Declaration of Conformity referred to in MDR Article 19
NA

Zertifikat: / Certificate:

Benannte Stelle: / Notified Body:

NA

Die Konformitätserklärung ist gültig bis: /
Declaration of Conformity is valid until: /

2025-03-11

Hangzhou, 2020-03-12

Place, date (地址/日期)

Ban Ming Yu
General Manager
Name and function (姓名/职务)



检测报告 (Test Report)

No. BOYNNW5R764407QA

样品名称 (Sample Description) Medical Face Mask 175mm*95mm

委托单位 (Applicant) 杭州山友医疗器械有限公司

PONY 谱尼测试
Pony Testing International Group
www.ponytest.com

检测结果 (Test Results)


No. BOYNNW5R764407QA 第 1 页, 共 2 页 (page 1 of 2)

样品名称 (Sample Description)	Medical Face Mask 175mm*95mm	样品规格 (Sample Specification)	---
委托单位 (Applicant)	杭州山友医疗器械有限公司	商标 (Trade Mark)	---
到样日期 (Received Date)	2020-03-11	生产日期或批号 (Manufacturing Date or Lot No.)	---
检测日期 (Test Date)	2020-03-11-2020-03-26	样品等级 (Sample Grade)	---
样品数量 (Sample Quantity)	40pcs	检测类别 (Test Type)	委托检测 (Commissioning Test)
样品状态 (Sample Status)	样品完好 The samples in good condition, Finished 成品	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 等 etc		
备注 (Note)	标准标准 Limit Standard: EN 14683: 2019 样品型号 Sample Model: 175mm*95mm 材质 Material: 无纺布 Non-woven and melt-blown fabrics. 适用领域 Application Field: 医疗领域 Application: 医疗 Medical		
	编制人 (Edited by)		
	审核人 (Checked by)		
	批准人 (Approved by)		
	签发日期 (Issue Date)		2020-03-26

Hotline 400-819-5688
www.ponytest.com

检测结果 (Test Results)

No. BOYNNW5R764407QA 第 2 页, 共 2 页 (page 2 of 2)

样品名称和编号 (Sample Description and Number)	检测项目 (Test Items)	标准 (Limit)		检测结果 (Test Results)	检测方法 (Test Methods)
		限值 I (Limit Type I)	限值 II (Limit Type II)		
R No.447041 Medical Face Mask 175mm*95mm	细菌过滤效率, % Bacterial Filtration Efficiency (BFE)	≥95	≥98	1 st 99.7 2 nd 99.7 3 rd 99.7 4 th 99.7	EN 14683: 2019
	压差, Pa Differential pressure	<40	<40	20	EN 14683: 2019
	抗湿能力, kPa Splash resistance	/	/	>16.0	EN 14683: 2019
	微生物渗透率, cfu/g Microbial penetration	<30	<30	<1	EN 14683: 2019
	样品编号和照片 (Sample Number and Photo)				



仅对报告照片中的样品负责
Pony authenticates the photo on original report only
以下空白 (End of Report)