



Product Service

认证证书

证书号. Q6 092238 0006 Rev. 01

证书持有者：**浙江卓亿工贸有限公司**
中华人民共和国浙江省衢州市开化县马金镇忻黄路26号
324307

生产场地：**浙江卓亿工贸有限公司**
中华人民共和国浙江省衢州市开化县马金镇忻黄路26号
324307

见证书认证范围

认证标志：



认证范围：**生产和分销：**
手术手套和检查手套

认证标准：**EN ISO 13485:2016**
医疗器械 - 质量管理体系 - 用于法规的要求
(ISO 13485:2016)
DIN EN ISO 13485:2016

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系（删除第7.3条款）。TÜV 南德集团检测及认证规则所有适用要求也须得到遵守。详情及证书有效期请见 www.tuvsud.com/ps-cert?q=cert:Q6_092238_0006_Rev_01

报告号：**SH2194901**
生效期：**2022-03-29**
有效期：**2025-03-01**

发证日期, 2022-03-29

Christoph Dicks

Head of Certification/Notified Body

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany
本证书是由具有法律效力的英文证书翻译而来

TUV®



Certificate

No. Q6 092238 0006 Rev. 01

Holder of Certificate: Zhejiang Zhuoyi Industrial & Trading Co., Ltd.
NO.26 XINHUANG ROAD, MAJIN TOWN
KAIHUA COUNTY
324307 QUZHOU CITY, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Zhejiang Zhuoyi Industrial & Trading Co., Ltd.
NO.26 XINHUANG ROAD, MAJIN TOWN, KAIHUA COUNTY,
324307 QUZHOU CITY, ZHEJIANG PROVINCE, PEOPLE'S
REPUBLIC OF CHINA
See Scope of Certificate

Certification Mark:



Scope of Certificate: Production and distribution of Surgical Gloves and Examination Gloves

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6_092238_0006_Rev_01

Report No.: SH2194901
Valid from: 2022-03-29
Valid until: 2025-03-01

Date, 2022-03-29
Christoph Dicks
Head of Certification/Notified Body

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 092238 0007 Rev. 01

Manufacturer:

**Zhejiang Zhuoyi Industrial & Trading
Co., Ltd.**

NO.26 XINHUANG ROAD, MAJIN TOWN
KAIHUA COUNTY
324307 QUZHOU CITY, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Zhejiang Zhuoyi Industrial & Trading Co., Ltd.
NO.26 XINHUANG ROAD, MAJIN TOWN, KAIHUA COUNTY,
324307 QUZHOU CITY, ZHEJIANG PROVINCE, PEOPLE'S
REPUBLIC OF CHINA

**Product
Category(ies):**

Surgical Gloves

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH19949EXT01

Valid from: 2020-01-10

Valid until: 2024-05-26

Date, 2020-01-10

Christoph Dicks
Head of Certification/Notified Body

Declaration of Conformity

Manufacturer: ZHEJIANG ZHUOYI INDUSTRIAL&TRADING CO., LTD
NO.26 XINHUANG ROAD, MAJIN TOWN, KAIHUA COUNTY,
324307, ZHEJIANG, CHINA

European Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Surgical Gloves

Specification:

Surgical Gloves	Sizes									
	5	5.5	6	6.5	7	7.5	8	8.5	9	9.5
Latex Powdered	AP50-LSG	AP55-LSG	AP60-LSG	AP65-LSG	AP70-LSG	AP75-LSG	AP80-LSG	AP85-LSG	AP90-LSG	AP95-LSG
Latex Powder-free	AF50-LSG	AF55-LSG	AF60-LSG	AF65-LSG	AF70-LSG	AF75-LSG	AF80-LSG	AF85-LSG	AF90-LSG	AF95-LSG

Tradename: ZHUOYI™

UMDNS Code: 11883

Classification (MDD, Annex IX): **Ila, Rule 6**

Conformity Assessment Route: **Annex V.3**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. Zhejiang Zhuoyi Industrial & Trading Co.,Ltd is exclusively responsible for the Declaration of Conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC).

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr.
65, 80339 München, Germany

NB Identification number: 0123

(EC) Certificate(s): G2 092238 0007 Rev.01

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2016-03-03

Place, Date of Issue: **Quzhou City, 2021-11-15**

Signature:

Name: **Shi Zhuoli**
Position: **Management Representative**

EC Declaration of Conformity
ZY/CE01-01(A/5)



Test Report

No.: QDHL2005004253MD-01

Date: JUN.05,2020

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ZHEJIANG ZHUOYI INDUSTRIAL & TRADING CO.,LTD[▲]
NO.26XUNHUANG ROAD,MAJIN,KAIHUA,ZHEJIANG,CHINA,324307

**THIS REPORT IS TO SUPERSEDE TEST REPORT NO.: QDHL2005004253MD, DATE: JUN.03,2020.
THE ORIGINAL REPORT SHALL BECOME INVALID AS OF THE DATE OF ISSUANCE OF THIS REPORT.**

The following sample(s) was/were submitted and identified by the client as:

Sample Description : STERILE LATEX SURGICAL GLOVES
Lot No. : NOT PROVIDED
Lot Size : NOT PROVIDED
Sample Quantity : 700PCS
Manufacturer : ZHEJIANG ZHUOYI INDUSTRIAL & TRADING CO.,LTD[▲]
Supplier : ZHEJIANG JOYEE INDUSTRY CO.,LTD[▲]
Sample Receiving Date : MAY.15,2020
Testing Period : MAY.15,2020 TO JUN.03,2020

Test Requested	Result
1. BS EN 455-1:2000 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes (Clause 5.1)	Pass
2. BS EN 455-2:2015 Medical Gloves for Single Use – Part 2: Requirements and Testing for Physical Properties (Clause 4.2, 4.3, 5.2, 5.3)	Pass

Remark: - Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

SGS-CSTC Standards
Technical Services (Qingdao)
Co., Ltd.

Jessica Gao



QDHL2005004253MD-01

Jessica Gao
Approved Signatory

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Test Conducted:

1. BS EN 455-1:2000 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes

Number of test sample	:	200 pcs
Sample Size	:	7
Number of non-conforming gloves	:	2 pcs

Clause	Test Items	Result
5	Watertightness test for detection of holes	---
5.1	Referee testing	Pass (See note 1)

Note : 1 Sample quantity: 200pcs, AQL:1.5, Ac:7, Re:8, Found:2pcs
The sample selecting amount for this clause is deviated to 200 pcs as assessed by SGS.

2. BS EN 455-2:2015 Medical gloves for single use – Part 2: Requirements and testing for physical properties

Number of test sample	:	26 Pieces
Type	:	Surgical gloves
Size	:	Surgical gloves:7

Clause	Test Items	Result
4	Dimensions	---
4.2	Length	Pass (See result 1)
4.3	Width	Pass (See result 1)
5	Strength	---
5.2	Force at break	Pass (See result 2)
5.3	Force at break after challenge testing	Pass (See result 2)

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Result 1: Dimensions

Size	7	
No.	Length (mm)	Width (mm)
1	281	90
2	280	90
3	279	89
4	278	89
5	278	90
6	279	90
7	280	89
8	279	89
9	281	90
10	273	90
11	282	90
12	283	90
13	278	90
Standard requirement	≥270	89±5
Median value	279	90

Result 2: Strength

Size: 7			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	15.4	1	14.6
2	16.1	2	14.6
3	16.8	3	16.0
4	15.5	4	15.3
5	17.5	5	14.9
6	17.5	6	13.5
7	16.8	7	16.2
8	17.5	8	15.3
9	18.3	9	16.3
10	17.9	10	16.8
11	16.1	11	15.6
12	15.6	12	15.6
13	16.3	13	15.7
Standard requirement	≥9.0	Standard requirement	≥9.0
Median value	16.8	Median value	15.6

Attention: To check the authenticity of testing / inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doccheck@sgs.com

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Remark:

- The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
- The marked▲part is the modification information.

Sample Photo:

Received Sample



SGS authenticate the photo on original report only

End of Report

Handwritten red stamp: 7/11/2020, 16:11:11



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