防疫物资/医用耗材/辐照灭菌

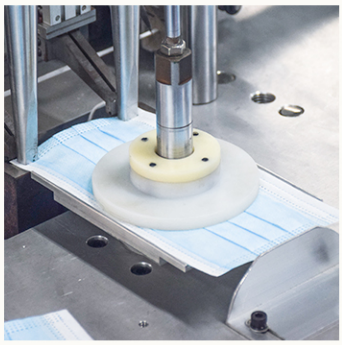
华福
HUAFU

FILTERING HALF MASK

FFP2半过滤面罩

华|福|资|料|册

通过ISO13485质量管理体系认证，
拥有TUV（南德意志）ISO13485质量管理体系认证和一系列CE产品认证。
拥有符合GMP标准的十万级净化车间



浙江华福医用器材有限公司 Zhejiang Huafu Medical Equipment Co., Ltd.
浙江·平湖 浙江省平湖市新兴一路688号 No. 688 Xinxing 1st Road, Pinghu City, Zhejiang Province, 314200China.
0573-85963333 Http://www.huafuzj.com E-mail : sales@huafuzj.com

营业执照
Business License

华福 HUAFU

统一社会信用代码

91330482148405063L (1/1)

营业执照
BUSINESS LICENSE OF LEGAL ENTITY
（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　浙江华福医用器材有限公司
Company Name: Zhejiang Huafu Medical equipment Co.,Ltd

类　　型　有限责任公司（自然人投资或控股）
Type: Limited Liability Company (Natural person investment or holding)

法定代表人　王维文
Legal Representative: Wang Weiwen

经营范围　一般项目：医护人员防护用品生产（Ⅰ类医疗器械）；第一类医疗器械生产；日用口罩（非医用）生产（除依法须经批准的项目外，凭营业执照依法自主开展经营活动）。许可项目：第三类医疗器械生产；卫生用品和一次性使用医疗用品生产；医用口罩生产；医护人员防护用品生产（Ⅱ类医疗器械）；第二类医疗器械生产；货物进出口；技术进出口（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，具体经营项目以审批结果为准）。

Business Scope General item: production of protective equipment for medical staff (Class I medical devices); production of Class I medical devices: production of daily-use masks (non-medical) (except for items subject to approval according to law, independent on business operation with business license). Licensed items: Production of Class III medical devices: sanitary products and production of disposable medical products: production of medical masks: production of protective equipment for medical staff (Class II medical devices); production of class II medical devices: import and export of goods: technology Import and export (items that are subject to approval in accordance with the law can only be carried out after the approval of the counter customs department, and the specific operation items are subject to the approval results).

注册资本　壹仟万元整
Registered capital: 10 million Yuan

成立日期　1994 年 08 月 24 日
Operating period: From 1994.08.24

营业期限　1994 年 08 月 24 日 至 2024 年 08 月 23 日
Found date: 1994.08.24 to 2024.08.23

住　　所　浙江省嘉兴市平湖市经济开发区新兴一路 688 号
Address: No. 688, Xinxing 1st Road, Pinghu, Zhejiang Province

登记机关
Registration Authority

Pinghu Market Supervision Administration

2020 年 02 月 28 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

浙江华福医用器材有限公司　Zhejiang Huafu Medical Equipment Co., Ltd.
浙江 · 平湖 浙江省平湖市新兴一路688号　No. 688 Xinxing 1st Road, Pinghu City, Zhejiang Province, 314200China.
0573-85963333　Http://www.huafuzj.com　E-mail : sales@huafuzj.com

对外贸易经营者备案登记表

备案登记表编号：04329048　　统一社会信用代码：91330482148405063L
进出口企业代码：

经营者中文名称	浙江华福医用器材有限公司		
经营者英文名称	ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.		
组织机构代码	----------	经营者类型（由备案登记机关填写）	有限责任公司
住　所	浙江省平湖市经济开发区新兴一路688号		
经营场所（中文）	浙江省平湖市经济开发区新兴一路688号		
经营场所（英文）	688 XINXING 1ST ROAD,ECONOMIC DEVELOPMENT ZONE, PINGHU,ZHEJIANG		
联系电话	0573-85963333	联系传真	0573-85155298
邮政编码	314200	电子邮箱	sales@huafuzj.com
工商登记注册日期	1994-8-24	工商登记注册号	----------

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	王维文	有效证件号	332627196209192196
注册资金	壹仟万元		（折美元）

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人／个体工商负责人姓名		有效证件号	
企业资产／个人财产			（折美元）

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

对外贸易经营者备案登记 备案登记机关 签章 (浙江平湖)

2019 年 09 月 29 日

华 福 ®
HUAFU

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1401

Respiratory protective devices, filtering half masks to protect against particles manufactured by
Zhejiang Huafu Medical Equipment Co., Ltd.

No. 688 Xinxing 1st Road, Pinghu City, Zhejiang Province, 314200 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.

Product Definition

Brand Name: - **Model:** HF8211
Filtering half mask
Classification: FFP2 NR

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 **02/09/2020** 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

Verify the validity with the QR code

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

美国FDA
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华 福 ®
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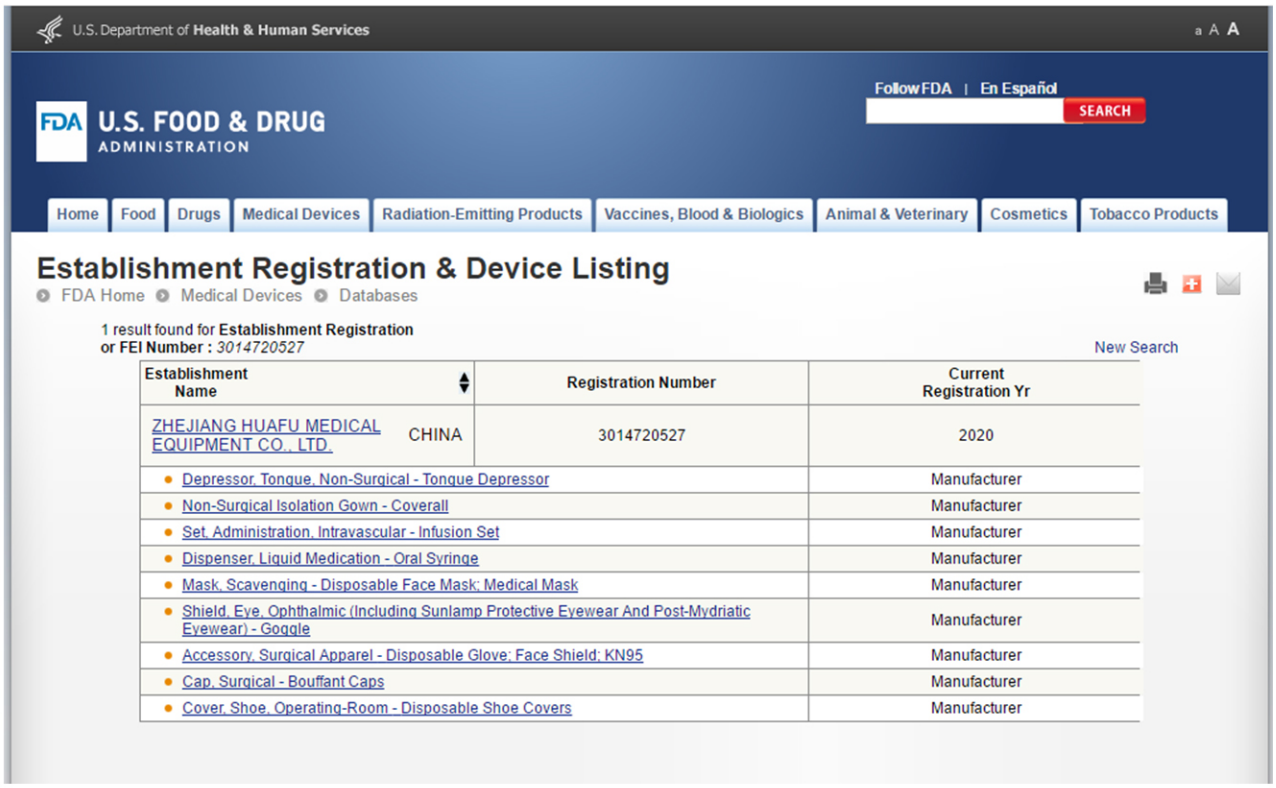

U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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Establishment Registration & Device Listing

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1 result found for **Establishment Registration** or FEI Number : *3014720527*

New Search

Establishment Name		Registration Number	Current Registration Yr
ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.	CHINA	3014720527	2020
• Depressor, Tongue, Non-Surgical - Tongue Depressor			Manufacturer
• Non-Surgical Isolation Gown - Coverall			Manufacturer
• Set, Administration, Intravascular - Infusion Set			Manufacturer
• Dispenser, Liquid Medication - Oral Syringe			Manufacturer
• Mask, Scavenging - Disposable Face Mask; Medical Mask			Manufacturer
• Shield, Eye, Ophthalmic (Including Sunlamp Protective Eyewear And Post-Mydriatic Eyewear) - Goggle			Manufacturer
• Accessory, Surgical Apparel - Disposable Glove; Face Shield; KN95			Manufacturer
• Cap, Surgical - Bouffant Caps			Manufacturer
• Cover, Shoe, Operating-Room - Disposable Shoe Covers			Manufacturer

CERTIFICATE

FDA

Fiscal Year 2020

CERTIFICATE OF FDA REGISTRATION

This certifies that

ZHEJIANG HUAFU MEDICAL EQUIPMENT CO.,LTD

NO.688 Xinxing 1st Rd., Pinghu, Jiaxing, Zhejiang Province, China

Has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through MEDISCA Inc

Owner/Operator Number:10058618

UNITED STATES AGENT

Contact Name: Jason Zhou
Contact Title: Mr
Business Name: Shamrock Import And Export INC

Address: 448 E Foothill Blvd STE 206, SanDimas, CA 91773 San Dimas , CA 91773
Phone: 626 6325067 Ext
E-mail: Lindaliu820211@Gmail.com

Listing No.	Premarket Submission Number/Type	Product Code(s)	Device Name	Activities
D408148	Exempt	FXP	COVER,SHOE,OPERATING-ROOM	Manufacturer
D407607	Exempt	FYF	CAP,SURGICAL	Manufacturer
D399549	Exempt	LYU	ACCESSORY,SURGICAL APPAREL	Manufacturer
D399412	Exempt	HOY	Shield,eye,ophthalmic(including sunlamp protective eyewear and post-mydriatic eyewear)	Manufacturer
D346787	K003854	FPA	Set,administration,intravascular	Manufacturer
D374391	Exempt	OEA	Non-surgical isolation gown	Manufacturer
D331226	Exempt	KYX	DISPENSER,LIQUID MEDICATION	Manufacturer
D352530	Exempt	FMA	DEPRESSOR,TONGUE,NON-SURGICAL	Manufacturer
D376645	Exempt	KHA	MASK,SCAVENGING	Manufacturer

Please careful protect your Listing Number.

Shamrock Import And Export INC
448 E Foothill Blvd STE 206,
SanDimas, CA US 91773

Cert. No.: M20323
Issued Date: 23 March 2020
Expiration Date: 31 December 2020

CERTIFICATE

U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

SEARCH

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机构注册和设备清单

FDA首页 ▸ 医疗设备 ▸ 资料库

找到1个 机构注册或FEI号的结果： *3014720527*

新搜寻

机构名称		注册号码	当前注册年份
浙江华福医用器材有限公司	中国	3014720527	2020年
• 压舌器，非手术舌头-压舌板			制造商
• 非手术隔离服-连体衣			制造商
• 集，输药，血管内-输液器			制造商
• 分配器，液体药物-口服注射器			制造商
• 口罩，清除一次性口罩；医用口罩			制造商
• 防护罩，眼睛，眼科（包括日光防护眼镜和取罐后眼镜）-Goggle			制造商
• 附件，外科服装一次性手套；面罩-KN95			制造商
• 手术帽-蓬松帽			制造商
• 鞋套，手术室一次性鞋套			制造商

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页面上次更新时间：06/15/2020

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美国食品药品监督管理局
10903 New Hampshire Avenue
Silver Spring，MD 20993 Ph.1-888
-INFO-FDA（1-888-463-6332）

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科学与研究

U.S. Department of Health & Human Services

浙江华福医用器材有限公司 Zhejiang Huafu Medical Equipment Co., Ltd.
浙江 · 平湖 浙江省平湖市新兴一路688号 No. 688 Xinxing 1st Road, Pinghu City, Zhejiang Province, 314200China.
☎ 0573-85963333 Http://www.huafuzj.com E-mail : sales@huafuzj.com

欧洲检测说明书
Test instructions

华 福
HUAFU

The User information of Filtering half mask

【Product Name & Model No.】

Filtering half mask against standard EN149:2001+A1:2009 to Regulation (EU) 2016/425, model HF8211

【Primary Structure】

It is mainly made of non-woven fabrics and melt-blown filter material.

【Use Range】

Filtering half mask is intended to be used as a single shift use particle filtering half masks for protection against solid and liquid aerosols.

【Warnings】

1. Before use the masks first verify that it is suitable for the intended use. The wearer must be adequately trained prior to use and ensuring the masks are proper fit.
2. The mask is disposable and cannot be reused.
3. Using the masks with facial hair will cause leakage problem, if the facial hair not covered, unlikely to achieve seal.
4. Discard and replace the mask if it becomes damaged or higher breathing resistance.
5. Don't use the mask in explosive gas, heavily polluted environment, oxygen-deficient environment, fire environment and the underwater work.
6. Patients with heart disease or other disease should discard it after wearing uncomfortably.
7. Masks marked '' NR'' shall not be used for more than one shift.
8. This product does not supply oxygen. Use only in adequately ventilated areas containing sufficient oxygen to support life. Do not use this respirator when oxygen concentration is less than 19.5%.
9. Do not use in explosive atmospheres.
10. It is strictly prohibited to use after the package is damaged.

【Using Instructions】

In structions

【Storage Condition and Methods】

1. The unused Masks needs to be stored in the environment that is well ventilated, dry and away from light. Keep away from fire, pollutants and potential source of pollution.
2. Storage temperature: -30℃ to 40℃ and less than 80% relative humidity.
3. Keep the masks in original packaging boxes when during transportation to protected against mechanical damage and contamination.

【Explanation about Signs, Symbols】

	Single use		Keep out of direct sunlight
<80%	Maximum relative humidity of storage conditions	-30℃ +40℃	The temperature range of storage conditions
	See the information provided by the manufacturer	CE 2163	CE mark and Notified Body No

【The Manufactured date】

Month / Year

【The Expiry time】

1 year

【Manufacturer & Address】

Zhejiang Huafu Medical Equipment Co., Ltd.

NO.688 Xinxing 1st Road, Pinghu City, Zhejiang Province, 314200China

Contact number：15068369999 Tel：0573-85963333

Fax：0573-85155298 Zip code：314200

E-mail : sales@huafuzj.com

The EU DoC is to be delivered with accompanies the user information and masks together.

【The Notified Body】

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

NB:2163

医疗器械生产许可证
Medical Device Production License

华福 HUAFU

医疗器械生产许可证

许可证编号：浙食药监械生产许 20100231 号

企业名称：浙江华福医用器材有限公司

生产地址：浙江省平湖市经济开发区新兴一路 688 号

法定代表人：王维文

生产范围：第 III 类 14-01 注射、穿刺器械；第 III、II 类 14-02 血管内输液器械；第 II 类 14-14 医护人员防护用品；第 II 类 14-13 手术室感染控制用品***

企业负责人：王维文

住　　所：平湖经济开发区新兴一路 688 号

发证部门：浙江省药品监督管理局

有效期限：至 2025 年 3 月 29 日

发证日期：2020 年 10 月 9 日

国家食品药品监督管理总局制

浙江华福医用器材有限公司 Zhejiang Huafu Medical Equipment Co., Ltd.
浙江 · 平湖 浙江省平湖市新兴一路688号 No. 688 Xinxing 1st Road, Pinghu City, Zhejiang Province, 314200China.
0573-85963333 Http://www.huafuzj.com E-mail : sales@huafuzj.com

管理体系认证
Management System Certification

华 福 ®
HUAFU

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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 090117 0013 Rev. 01

Manufacturer: ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD.
314200 PINGHU, JIAXING, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):
Disposable Syringe with Needle,
Hypodermic Needle, Infusion Set,
Blood Transfusion Set,
Burette Infusion Set,
Insulin Syringe, Scalp Vein Set,
Heparin Caps,
Three-Way Stopcocks (with Extension Tube),
Sterile Blood Lancets,
Disposable IV Catheter,
Disposable Medical Protective Clothing (PPE),
Disposable Isolation Gown

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.: SH19941EXT01

Valid from: 2020-02-04
Valid until: 2024-05-26

Date, 2019-12-20

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q8 090117 0014 Rev. 00

Holder of Certificate: ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD.
314200 PINGHU, JIAXING, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD., 314200 PINGHU, JIAXING, ZHEJIANG PROVINCE, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: ETO Sterilization Service for Medical Devices

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, 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:Q8 090117 0014 Rev. 00

Report No.: SH2094101

Valid from: 2020-08-31
Valid until: 2021-02-03

Date, 2020-08-31

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q6 090117 0011 Rev. 01

Holder of Certificate: ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD.
314200 PINGHU, JIAXING, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD., 314200 PINGHU, JIAXING, ZHEJIANG PROVINCE, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: Production and Distribution of
Syringe, Hypodermic needle,
Infusion & transfusion set,
Scalp vein set, Irrigation syringe,
Oral syringe, Heparin Caps,
Three-way Stopcocks (with Extension Tube),
Sterile Blood Lancets, Disposable IV Catheter,
Sterile Vaginal Dilators for Single Use,
Wound Dressings, Urine Bags

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). Il 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 090117 0011 Rev. 01

Report No.: SH2094101
Valid from: 2020-08-31
Valid until: 2021-02-03

Date, 2020-08-31

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Supplement to Quality System Certificate

No. SUP 090117 0015 Rev. 00

This supplement is only valid in conjunction with the main certificate: Q8 090117 0014 Rev. 00

Certificate Holder: ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD.
314200 PINGHU, JIAXING, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD., 314200 PINGHU, JIAXING,
ZHEJIANG PROVINCE, PEOPLE'S REPUBLIC OF CHINA

The quality system certified as stated in the main certificate additionally fulfills the applicable requirements of

EN ISO 11135:2014 "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)"

Audit Report: SH2094101
Dated: 2020-01-07

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization

Valid from: 2020-08-31

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH · Certification Body · Ridlerstrasse 65 · Munich · Germany

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浙江华福医用器材有限公司 Zhejiang Huafu Medical Equipment Co., Ltd.
浙江 · 平湖 浙江省平湖市新兴一路688号 No. 688 Xinxing 1st Road, Pinghu City, Zhejiang Province, 314200China.
☎ 0573-85963333 Http://www.huafuzj.com E-mail : sales@huafuzj.com

管理体系认证
Management System Certification

华福 HUAFU

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT ◆ 認證證書

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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 090117 0013 Rev. 01

Manufacturer: ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD.
314200 PINGHU, JIAXING, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):
Disposable Syringe with Needle,
Hypodermic Needle, Infusion Set,
Blood Transfusion Set,
Burette Infusion Set,
Insulin Syringe, Scalp Vein Set,
Heparin Caps,
Three-Way Stopcocks (with Extension Tube),
Sterile Blood Lancets,
Disposable IV Catheter

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.: SH19941EXT01

Valid from: 2020-02-04
Valid until: 2024-05-26

Date, 2019-12-20

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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 090117 0013 Rev. 01

Facility(ies): ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD., 314200 PINGHU, JIAXING, ZHEJIANG PROVINCE, PEOPLE'S REPUBLIC OF CHINA

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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 I in sterile conditions, sterilised systems or procedure packs)

No. G2S 090117 0012 Rev. 01

Manufacturer ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD.
314200 PINGHU, JIAXING, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):
Irrigation Syringe,
Oral Syringe,
Sterile Vaginal Dilators for Single Use,
Wound Dressings,
Urine Bags

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH19941EXT01

Valid from: 2020-02-04
Valid until: 2024-05-26

Date, 2019-12-20

Christoph Dicks
Head of Certification/Notified Body

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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 I in sterile conditions, sterilised systems or procedure packs)

No. G2S 090117 0012 Rev. 01

Facility(ies): ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD., 314200 PINGHU, JIAXING, ZHEJIANG PROVINCE, PEOPLE'S REPUBLIC OF CHINA

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华 福 ®
HUAFU

FILTERING HALF MASK

FFP2半过滤面罩

CE

浙嘉食药监械生产备20170011号
Zhejiang Jiaxing Food and Drug Administration Production Reg.No.20170011
浙嘉械备20200053号
Zhejiang Medical Products Jiaxing Reg.No.20200053

检验检测报告
TEST REPORT

STFWT202017309

Product Name: Filtering half mask

Trust Unit: Universal Certification and Surveillance Service Trade Ltd. Co.

Manufacturer: Zhejiang Huafu Medical Equipment Co., Ltd.

Test Category: Entrusted Inspection

江苏省特种安全防护产品质量监督检验中心
JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

Test Report

STFWT202017309

Product Name	Filtering half mask	Specification Type	HF8211
		Trademark	——
Trust Unit	Universal Certification and Surveillance Service Trade Ltd. Co.	Tel.	13255833962
Manufacturer	Zhejiang Huafu Medical Equipment Co., Ltd.	Sample Grade	FFP2
Sample Quantity	70 pcs	Sample Receiving Date	2020-07-28
Test Category	Entrusted inspection	Batch No./Article No	——
Samples Conditions	Meet the testing requirements		
Document and Decide Accordance	EN 149：2001+A1：2009《*Respiratory protective devices -Filtering half masks to protect against particles-Requirements，testing，marking*》		
Test Conclusion	The samples were tested, the items tested meet the requirements of EN 149:2001+A1:2009 standard for FFP2 level. Signature Date：2020-08-20		
Remarks	The head harness of the mask provided by the applicant is ear hanging. Compatibility with skin is not recognized by the center. The test data are only for reference. The sample is not marked for reuse（NR）and does not require testing for blocking performance. The test conclusion of this report is only for the items inspected and does not mean that the uninspected items or functions meet the requirements. The results apply to the sample as received.		

Approver 筱婷 Examiner 杨森 Major tester 丁依

7.3 Visual inspection N/R

The visual inspection shall include the marking and information supplied by the manufacturer.

7.4 Package Pass

Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.

7.5 Material Pass[1]

Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the face piece or straps.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Note1: Refer to Annex A for test data.

7.6 Cleaning and disinfecting N/A[2]

If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.

Note2: Non-reusable respirator.

7.7 Practical performance Pass[3]

The particle filtering half mask shall undergo practical performance tests under realistic conditions.

Note3: Refer to Annex A for test data.

7.8 Finish of parts Pass

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

7.9.1 Total inward leakage Pass[4]

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e.10 subjects×5 exercises) for total inward leakage shall be not greater than:

25% for FFP1, 11% for FFP2, 5% for FFP3 .

In addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than:

22% for FFP1, 8% for FFP2, 2% for FFP3.

Note4: Refer to Annex A for test data.

Subject facial dimensions:

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
YS	115	159	115	48
ZJ	118	165	118	51
WL	117	157	113	49
LQM	98	141	101	53
ZYS	99	147	107	47
WP	119	169	120	55
YYW	112	151	115	56
CYW	105	148	108	51
DX	113	162	116	57
DHJ	103	149	105	56

7.9.2 Penetration of filter material Pass[5]

The penetration of the filter of the particle filtering half mask shall meet the requirements of the table.

	Sodium chloride test 95 L/min	Paraffin oil test 95 L/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note5: Refer to Annex A for test data.

7.10 Compatibility with skin Pass[6]

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

Note6: Refer to Annex A for test data.

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7.11 Flammability Pass[7]

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame.

Note7: Refer to Annex A for test data.

7.12 Carbon dioxide content of the inhalation air Pass[8]

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume)。

Note8: Refer to Annex A for test data.

7.13 Head harness Pass[9]

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering

half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

Note9: Refer to Annex A for test data.

7.14 Field of vision Pass[10]

The field of vision is acceptable if determined so in practical performance tests.

Note10: Refer to Annex A for test data.

7.15 Exhalation valve N/A[11]

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.

Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

Note11: Valve-less respirator.

7.16 Breathing resistance Pass[12]

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 L/min	95 L/min	160 L/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Note12: Refer to Annex A for test data.

7.17 Clogging N/A[13]

7.17.2 Breathing resistance N/A[13]

Valved particle filtering half masks:

After clogging the inhalation resistances shall not exceed:

FFP1: 4 mbar, FFP2:5 mbar, FFP3: 7 mbar at 95L/min continuous flow

The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow

Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed:

FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow

7.17.3 Penetration of filter material N/A[13]

Classification	Sodium chloride test 95 L/min	Paraffin oil test 95 L/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note13: Non-reusable respirator.

7.18 Demountable parts N/A[14]

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand

Note14: No demountable parts.

9 Marking N/R

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.1.2 Type-identifying marking.

9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.1.4 The number and year of publication of this European Standard.

9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.

9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.

9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d

9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". !This letter shall follow the classification marking preceded by a single space.

9.2 Particle filtering half mask

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering

half mask is limited to single shift use only.

Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable.

Example: FFP2 R D.

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

10 Information to be supplied by the manufacturer N/R

10.1 Information supplied by the manufacturer shall accompany every smallest commercial available package.

10.2 Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.

10.3 The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on

-application/limitations;

-the meaning of any colour coding;

-checks prior to use;

-donning, fitting;

-use;

-maintenance (e.g. cleaning, disinfecting), if applicable;

-storage;

-the meaning of any symbols/pictograms used of the equipment.

10.4 The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.

10.5 Warning shall be given against problems likely to be encountered, for example:

-fit of particle filtering half mask (check prior to use);

-it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;

-air quality (contaminants, oxygen deficiency);

-use of equipment in explosive atmosphere.

10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded.

10.7 For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift.

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Annex A: Summarization of Test Data

Clause		Result								Assessment
7.5	Material	Simulated wearing treatment	1#	No mechanical failure						Pass
			2#	No mechanical failure						
			3#	No mechanical failure						
		Temperature conditioned	4#	No mechanical failure						
			5#	No mechanical failure						
			6#	No mechanical failure						
7.9	Practical performance	As received	7#	No mechanical failure						Pass
			8#	No mechanical failure						
7.9.1	Total inward leakage (%)		Sample No	Walk	Head (side/side)	Head (up/down)	Talk	Walk	Mean	Pass
		As received	9#	7.4	7.6	7.7	7.1	6.8	7.3	
			10#	6.8	7.6	7.7	7.0	6.4	7.1	
			11#	6.7	7.4	8.1	7.5	6.4	7.2	
			12#	7.3	12.4	13.3	12.9	7.3	10.6	
			13#	6.2	6.3	7.0	6.3	5.7	6.3	
		Temperature conditioned	14#	6.1	6.3	6.6	6.2	5.7	6.2	
			15#	6.6	6.6	7.5	6.6	6.0	6.7	
			16#	6.2	6.4	6.4	6.1	6.0	6.2	
			17#	5.9	6.0	7.0	7.0	5.1	6.2	
			18#	7.5	7.7	8.5	8.5	7.0	7.8	
			Individual exercise result : 47 out of the 50 individual exercise results ≤ 11 Individual wearer arithmetic means : 9 individual wearer arithmetic means≤ 8							

Clause		Result			Assessment
7.9.2	Penetration of filter material/%	Sodium chloride test(95L/min)			Pass
		As received	19#	0.09	
			20#	0.17	
			21#	0.15	
		Simulated wearing treatment	22#	0.24	
			23#	0.29	
			24#	0.32	
		M.S.+T.C.	25#	0.37	
			26#	0.42	
			27#	0.49	
		Paraffin oil test(95L/min)			
		As received	28#	0.58	
			29#	0.67	
			30#	0.64	
		Simulated wearing treatment	31#	0.73	
			32#	0.77	
			33#	0.84	
		M.S.+T.C.	34#	0.97	
			35#	1.14	
			36#	1.08	
7.10	Compatibility with skin	As received	9#	No irritation or any other adverse effect to health	Pass
			10#	No irritation or any other adverse effect to health	
			11#	No irritation or any other adverse effect to health	
			12#	No irritation or any other adverse effect to health	
			13#	No irritation or any other adverse effect to health	
		Temperature conditioned	14#	No irritation or any other adverse effect to health	
			15#	No irritation or any other adverse effect to health	
			16#	No irritation or any other adverse effect to health	
			17#	No irritation or any other adverse effect to health	
			18#	No irritation or any other adverse effect to health	
7.11	Flammability	As received	37#	burn for 0.5 s	Pass
			38#	burn for 0.4 s	
		Temperature conditioned	39#	burn for 0.8 s	
			40#	burn for 0.7 s	

Clause		Result				Assessment
7.12	Carbon dioxide content of the inhalation air/%	As received				Pass
		41#	42#	43#	Mean value	
		0.52	0.51	0.54	0.52	
7.13	Head hardness	As received				Pass
		9#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		10#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		11#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		12#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		13#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		Temperature conditioned				
		14#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		15#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		16#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		17#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		18#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
7.14	Field of vision	As received	7#	Passed the practical performance tests		Pass
			8#	Passed the practical performance tests		

Clause		Result					Assessment
7.16	Breathing resistance (mbar)			Inhalation 30 L/min	Inhalation 95 L/min	Exhalation 160 L/min	Pass
		As received					
		41#	A	0.3	1.0	1.5	
			B	0.3	1.0	1.5	
			C	0.3	1.0	1.6	
			D	0.3	1.1	1.5	
			E	0.3	1.0	1.5	
		42#	A	0.3	1.0	1.5	
			B	0.3	1.1	1.5	
			C	0.3	1.0	1.5	
			D	0.3	1.0	1.6	
			E	0.3	1.0	1.5	
		43#	A	0.3	1.0	1.5	
			B	0.3	1.0	1.6	
			C	0.3	1.0	1.5	
			D	0.3	1.1	1.5	
			E	0.3	1.0	1.5	
		Simulated wearing treatment					
		44#	A	0.3	1.0	1.5	
			B	0.3	1.0	1.5	
			C	0.3	1.1	1.6	
			D	0.3	1.0	1.5	
			E	0.3	1.0	1.5	
		45#	A	0.3	1.0	1.5	
			B	0.3	1.0	1.5	
			C	0.3	1.0	1.5	
			D	0.3	1.1	1.6	
			E	0.3	1.0	1.5	
		46#	A	0.3	1.0	1.5	
			B	0.3	1.1	1.5	
			C	0.3	1.0	1.5	
			D	0.3	1.0	1.5	
			E	0.3	1.0	1.6	

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☎ 0573-85963333 Http://www.huafuzj.com E-mail : sales@huafuzj.com

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Clause				Result			Assessment
				Inhalation		Exhalation	
				30 L/min	95 L/min	160 L/min	
		Temperature conditioned					
7.16	Breathing resistance	47#	A	0.3	1.0	1.5	Pass
			B	0.3	1.0	1.5	
			C	0.3	1.0	1.6	
			D	0.3	1.1	1.5	
			E	0.3	1.0	1.5	
		48#	A	0.3	1.0	1.5	
			B	0.3	1.1	1.6	
			C	0.3	1.0	1.5	
			D	0.3	1.0	1.5	
			E	0.3	1.0	1.5	
		49#	A	0.3	1.0	1.5	
			B	0.3	1.0	1.5	
			C	0.3	1.0	1.5	
			D	0.3	1.1	1.6	
			E	0.3	1.0	1.5	
7.16	Breathing resistance	A: facing directly ahead B: facing vertically upwards C: facing vertically downwards D: lying on the left side E: lying on the right side					

Remarks : M.S.: Mechanical strength; T.C.: Temperature conditioning; N/R: The clauses were not requested; N/A: Not applicable;

Original Sample

======= End of Report =======

JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS.

注 意 事 项

1、检验检测报告无“检验检测报告专用章”或检验检测单位公章无效。
2、复制检验检测报告未重新加盖检验检测报告专用章无效。
3、检验检测报告无主检、审核、批准人签字无效。
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地址：江苏省泰州市高港区临港经济园临港大道 166 号
Add: Lingang Road 166, Lingang Economic Park , Gaogang, Taizhou.Jiangsu
电话（ Tel ）: 0523–86989959
0523–86989939
邮编（ Post ）: 225300
网址（ Web ）: www.jstfzx.com
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规格 Size：61.5X35.5X61.5 cm
体积 Volume：0.134 m^3
毛重 G.W.：11.2 KG
净重 N.W.： 6 KG

货运装柜规格 Cargo loading specifications

产品规格 Sizepecification	包装数量 QTY	20尺柜 20 GP	40尺高柜 40 HQ
10.5X16 cm	**1000 pcs/箱Ctn**	**180000**	**480000**

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浙江·平湖 浙江省平湖市新兴一路688号 No. 688 Xinxing 1st Road, Pinghu City, Zhejiang Province, 314200China.
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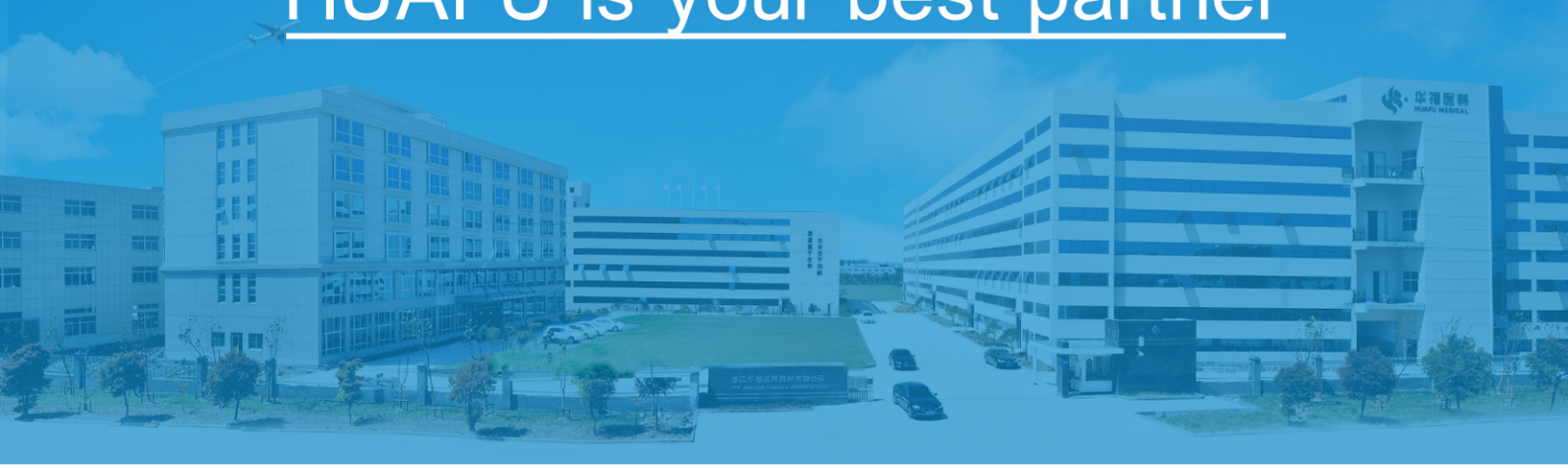

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Zhejiang Huafu Medical Equipment Co., Ltd.

浙江 · 平湖

浙江省平湖市新兴一路688号

No. 688 Xinxing 1st Road, Pinghu City,
Zhejiang Province, 314200China.

0573-85963333

Http://www.huafuzj.com

E-mail : sales@huafuzj.com