

## COMPANY PROFILE

## 公司简介



常州好利医疗集团,坐落江苏省常州市武进高新技术 产业开发区。公司占地面积12万平方米,员工近2000人, 拥有高标准的净化车间及先进的加工制造中心,市场营销网 络遍布国内外。

好利医疗集团无纺布医用品事业部始创于1980年,是 中国首批无纺布医用品的生产制造商,2003年公司获得 SARS防疫物资优秀生产单位的荣誉称号,2020年公司被 列为COVID-19病毒国家防疫物资重点生产企业。目前公 司是国内少数能生产四级手术衣的厂家之一。2011年公司 首次获得FDA认证,2012年取得手术衣510K的认证。四十 年来,HOLYMED在为全球知名品牌的OEM生产中积累了 丰富的品控质量经验。

Holymed Medical Group, establishing in the year of 1980, is located in Wujin high-tech industrial development zone at the national level, Changzhou, Jiangsu, China. The company covers an area of more than 120,000 square meters, nearly 2000 employees, has a high standard of purification workshop and advanced processing and manufacturing center, marketing network all over at home and abroad.

Holymed Medical Group non-woven medical prodcuts Division, establishing in the year of 1980, is one of the first manufacturers which produce non-woven medical products in China. In 2003, Holymed was awarded as outstanding manufacturer enterprise of anti-epidemic materials for SARS . In 2020, Holymed was listed as one of the national key manufacturer enterprise of anti-epidemic materials for COVID-19. Currently Holymed is one of the few domestic manufacturers that can produce AMMI level 4 surgical gowns. In 2011, Holymed obtained the FDA certification, and in 2012, Holymed passed the 510K certification for surgical gowns. For over 40 years, Holymed has accumulated rich experience in quality control for OEM production for international famous brands.





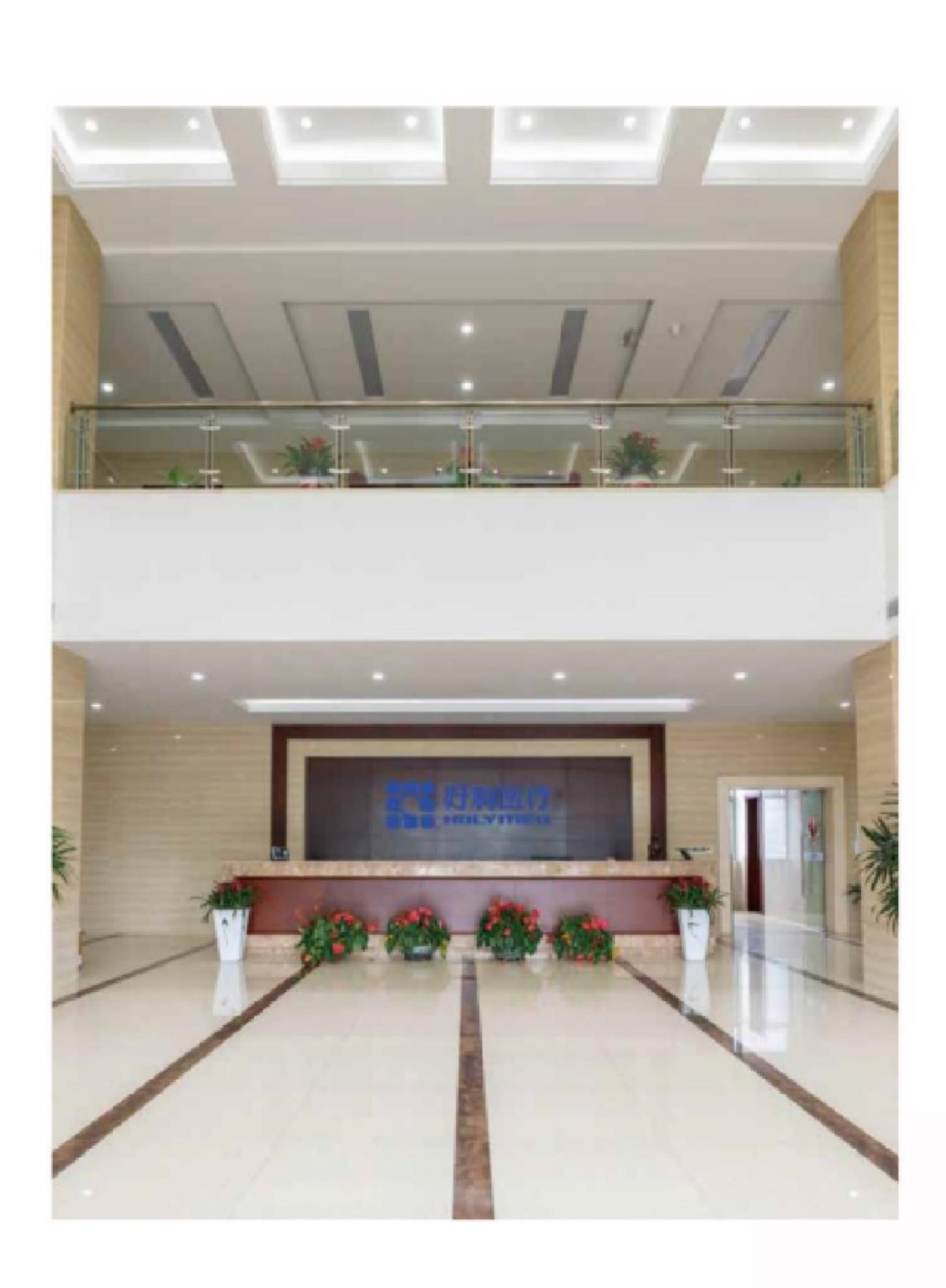






### PRODUCTION WORKSHOP





## 营业执照 Business License

# 医疗器械生产许可证证 Medical device production License



慶疗器機能产许可证

企业名称: 常州合力迈德医疗用品有限公司

法定代表人: 周水英

企业负责人: 伍晓明

武进国家高新技术产业区常武

许可证编号: 苏药监械生产许应急20200039号

生产地址:南路525号3号楼3楼

生产范围: 见医疗器械生产产品登记表

国家食品药品监督管理总局制

http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。







SEARCH

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Medical Devices

Radiation-Emitting Products

Vaccines, Blood & Biologics

Animal & Veterinary

Cosmetics

Tobacco Products

## Establishment Registration & Device Listing

FDA Home Medical Devices Databases









1 result found for Establishment Registration

or FEI Number: 3006891803

New Search

Establishment Name	Redistration Number					
CHANGZHOU HOLYMED PRODUCTS CO., LTD	3006891803	2021				
<ul> <li>Cover, Shoe, Operating-Room - Shoe Co</li> </ul>	rers, Boot Covers, Arm Covers	Contract Manufacturer; Manufacturer				
<ul> <li>Accessory, Surgical Apparel - Barrier Slee Shirts/Pants; Stethoscope Cover</li> </ul>	ve; Isolation Mask; Lab Coats, Coveralls; Scurb	Contract Manufacturer; Manufacturer				
<ul> <li>Non-Surgical Isolation Gown - Ortho Short</li> </ul>	ts	Contract Manufacturer; Manufacturer				
<ul> <li>Cap, Surgical - Nonwoven Caps, Bouffant</li> </ul>	Caps, Surgical Caps	Contract Manufacturer; Manufacturer				
Gown, Surgical	Contract Manufacturer					
<ul> <li>Show all 22 Listings For CHANGZHOU HOLYMED PRODUCTS CO., LTD CHINA</li> </ul>						

Can't find what you're looking for? Try a new search

Page Last Updated: 11/30/2020

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسى English

#### DRLM Home (mainMenu.htm) > Change Registration Information for a Facility

✓ Facility ✓ Products Listing

#### Registration Review

Facility: CHANGZHOU HOLYMED PRODUCTS CO., LTD, CHANGZHOU, Jiangsu, CHINA

- Review the information that you provided for your facility.
- Make changes to your facility or listing information by clicking the Edit button at the top of the corresponding section.
- · Make changes to Owner/Operator or Official Correspondent information by clicking on FURLS HOME at the top right corner of your screen.

#### **Facility Information**

1/6

Registration Number:

Initial Importer:

Facility Name: CHANGZHOU HOLYMED PRODUCTS CO., LTD Address: 525 CHANGWU ROAD SOUTH, WUJIN DISTRICT

3006891803

CHANGZHOU, Jiangsu, 213167, CHINA

Foreign Trade Zone:

Facility URL:

DUNS Number:

Other Business Trade Name(s):

#### Owner/Operator Information

Owner/Operator Number: 10024103 XIAOMING WU Contact Name:

CHANGZHOU HOLYMED PRODUCTS CO., LTD Company: Address: 525 CHANGWU ROAD SOUTH , WUJIN DISTRICT

CHANGZHOU, JIANGSU, 213167, CHINA

https://www.access.fda.gov/drlm/drlm.htm?\_flowExecutionKey=\_c4F7D8A39-2CD2-C320-4B1A-5E18B02AD6D5\_k832FCD90-BA7D-528B-8CB4-FF8FE50A350F

2020/1/19

Review Registration Screen

D108437	Exempt	FME	GOWN, EXAMINATION	Contract Manufacturer	PRECEPT MEDICAL PRODUCTS, INC.
					GMAX Industries, Inc.
D227166	K070431	FYA	GOWN, SURGICAL	Contract Manufacturer	Welmed Inc
D339379	Exempt	BWP	SHOE AND SHOE COVER, CONDUCTIVE	Contract Manufacturer	OWENS & MINOR DISTRIBUTION, Inc. H-OFFICE
					O&M HALYARD, INC.
					O&M Halyard, Inc.
					O&M HALYARD, INC.
D300777	Exempt	PUI	Drape, surgical, exempt	Contract Manufacturer	CARDINAL HEALTH 200, LLC
D242222	K012984	FYA	GOWN, SURGICAL	Contract Manufacturer	CARDINAL HEALTH 200, LLC

Review Registration Screen 2020/1/19

> Telephone: 086 - 519 - 86465859 086 - 519 - 86465969 Fax: E-mail:

**DUNS Number:** 

xiaoming.wu@holymed.com.cn

xiaoming.wu@holymed.com.cn

#### Official Correspondent Information

XIAOMING WU Contact Name:

Company: CHANGZHOU HOLYMED PRODUCTS CO., LTD Address: 525 CHANGWU ROAD SOUTH , WUJIN DISTRICT CHANGZHOU, JIANGSU, 213167, CHINA

Telephone: 086 - 519 - 86465859 086 - 519 - 86465969 Fax:

E-mail: **DUNS Number:** 

**United States Agent Information** 

Michael Sheppard Contact Name:

Contact Title:

**Business Name:** Address:

8710 Midnight Pass Rd., #405B Sarasota, Florida, 34242, UNITED STATES

Phone: 224 - 4364501

Fax: **DUNS Number:** 

E-mail: mikes@alliantietech.com

#### Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers
D222024	K023167	FYA	GOWN, SURGICAL	Contract Manufacturer	Cardinal Health 200, LLC

https://www.access.fda.gov/drlm/drlm.htm?\_flowExecutionKey=\_c4F7D8A39-2CD2-C320-4B1A-5E18B02AD6D5\_k832FCD90-BA7D-528B-8CB4-FF8FE50A350F

2020/1/19

D032483 Exempt		32483 Exempt FYF	CAP, SURGICAL	Contract Manufacturer	O&M HALYARD, INC.
					O&M Halyard, Inc.
					Broadline Medical Inc
					OWENS & MINOR DISTRIBUTION, Inc. H-OFFICE
					O&M HALYARD, INC.
D032484 Exempt		COVER, SHOE, OPERATING- ROOM	Contract Manufacturer	OWENS & MINOR	
					Inc. H-OFFICE
D032485	Exempt	OEA	Non-surgical isolation gown	Contract Manufacturer	Dyad Medical Sourcing, LLC
					O&M Halyard, Inc.
					O&M HALYARD, INC.
					OWENS & MINOR DISTRIBUTION, Inc. H-OFFICE
					O&M HALYARD INC.

D032486	Exempt	LYU	ACCESSORY, SURGICAL	Manufacturer	Medegen
			APPAREL	Contract	Medical Products
				Manufacturer	Dyad Medical
					Sourcing, LLC
					GMAX Industries Inc.
					Cardinal Health 200, LLC
D161458	K020593	FYA	GOWN, SURGICAL	Contract Manufacturer	Cardinal Health 200, LLC
D126847	K061308	FYA	GOWN, SURGICAL	Contract	Cardinal Health
				Manufacturer	200, LLC
D259734	K150151	FYA	GOWN, SURGICAL	Contract	CARDINAL
				Manufacturer	HEALTH 200, LLC
D235575	Enforcement	LRO	General surgery tray	Contract	CARDINAL
	Discretion			Manufacturer	HEALTH 200, LLC
D301757	K170762	FYA	GOWN, SURGICAL	Contract	CARDINAL
				Manufacturer	HEALTH 200, LLC
D335680	Exempt	KME	BEDDING, DISPOSABLE,	Contract	GMAX Industries
			MEDICAL	Manufacturer	Inc.

#### Certification Statement

By clicking the Submit button, I certify that the registration and listing information for this medical device facility, as shown on this page, is true. I understand that the submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.

#### DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

December 20, 2012

Mr. Alan Yu
Manager, Quality Assurance/Regulatory Affairs
Changzhou Holymed Products Company, Limited
528 Changwu Road South
Wujin District
Changzhou, Jiangsu, China 213167

Re: K121998

Trade/Device Name: HM Surgical Gowns Regulation Number: 21 CFR 878.4040 Regulation Name: Surgical Apparel

Regulatory Class: II
Product Code: FYA
Dated: November 27, 2012
Received: November 29, 2012

#### Dear Mr. Yu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Page 2 – Mr. Yu

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <a href="http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm">http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm</a> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <a href="http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm">http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm</a>.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and

**Dental Devices** 

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

#### INDICATIONS FOR USE

510(k) Number (if known): <u>K1219</u>98

Device Name: HM Surgical Gowns

#### Indications for Use:

HM Surgical gowns are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of micro-organisms, body fluids, and particulate matter.

HM Surgical Gowns are disposable, single use, sterile or nonsterile surgical gowns manufactured from nonwoven Spunbond-Meltblown-Spunbond (SMS) polypropylene fabrics.

Non-sterile HM surgical gowns are to be sold to repackager/relabeler establishments for EtO sterilization according to ISO 11135-1 and Sterile surgical gowns are to be sold directly to users after EtO sterilization validation to ISO 11135-1.

#### Gowns are provided as below:

#### Gown Family A: 960100/860100

PROD. CODE	STERILE/NONSTERILE	DESC.	SIZE	COLOR
	STERILE	Surgical Gown, Non Reinforced	M	BLUE
	STERILE	Surgical Gown, Non Reinforced		BLUE
	STERILE	Surgical Gown, Non Reinforced	XE	BLUE
980105	STERILE	Surgical Gown, Non Reinforced	XXL	BLUE
860102	NONSTERILE	Surgical Gown, Non Reinforced	М	BLUE
860103	NONSTERILE	Surgical Gown, Non Reinforced	L	BLUE
860104	NONSTERILE	Surgical Gown, Non Reinforced	XL	BLUE
860105	NONSTERILE	Surgical Gown, Non Reinforced	XXL	BLUE

Page 1 of 2

Gown Family B: 960200/860200 COLOR DESC. STERILE/NONSTERILE PROD. CODE BLUE Surgical Gown, Fabric Reinforced M. 960202 STERILE BLUE Surgical Gown, Fabric Reinforced L STERILE 960203 BLUE Surgical Gown, Fabric Reinforced XL 960204 STERILE BLUE Surgical Gown, Fabric Reinforced XXL 960205 STERILE BLUE Surgical Gown, Fabric Reinforced M NONSTERILE 860202 BLUE Surgical Gown, Fabric Reinforced NONSTERILE 860203 BLUE Surgical Gown, Fabric Reinforced XL NONSTERILE 860204 BLUE Surgical Gown, Fabric Reinforced XXL NONSTERILE 860205 Gown Family C: 960300/86000 COLOR

PROD. CODE	STERILE/NONSTERILE	DESC.	SIZE	COLOR
960302	STERILE	Surgical Gown, Poly Reinforced	to the second second	BLUE
السيافين والبراوان والمستفاد والمستفاد والمستفاد والمستفاد والمستفاد والمستفاد والمستفاد والمستفاد والمستفاد	STERILE		L	BLUE
960304 #	<u> </u>	<del></del>	- Ab	BLUE
960306	STERILE		XL, X-Long	BLUE
860302	NONSTERILE	Surgical Gown, Poly Reinforced	M	BLUE
860303	NONSTERILE	Surgical Gown, Poly Reinforced	L	BLUE
860304	<u> </u>	Surgical Gown, Poly Reinforced	XL	BLUE
860306	NONSTERILE	Surgical Gown, Poly Reinforced	XL, X-Long	BLUE

Prescription Use \_\_\_\_\_(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (21 CFR 801 Subpart C)

#### (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 2 of 2

Elizabeth F. Claverie 2012.12.19 21:51:29 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: 12/98

手术衣 Surgical Gown



规格	身长(cm)	周长(cm)	袖长(cm)	领深(cm)	肩宽(cm)	袖洞(cm)
S	110	135	56	9	18	28
M	115	145	59	9	19	29
L	137	157	61	9.4	20	30
XL	142	162	61	9.4	21.6	32
XXL	145	168	61	9.4	22.3	32

## 手术衣检测报告(美标,四级)

## Surgical Gown Test Report (SMMS LEVEL 4)







中国认可 国际互认 检测 TESTING CNAS L0599

**Test Report** 

SL52035272103001TX

Date:October 27,2020

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CHANGZHOU HOLYMED PRODUCTS CO., LTD.

525 CHANGWU ROAD SOUTH, WUJIN DISTRICT CHANGZHOU, JIANGSU, 213167, CHINA

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

Sample Description : (A)Surgical Gown

Composition : (A)Level 4
Sample Color : (A)Blue

Manufacturer : CHANGZHOU HOLYMED PRODUCTS CO., LTD.
Supplier : CHANGZHOU HOLYMED PRODUCTS CO., LTD.

Sample Receiving Date : Jul 09, 2020

Testing Period : Jul 09, 2020 - October 27,2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the

sample(s) tested, for further details, please refer to the following page(s).

Test Performed : Selected test(s) as requested by applicant

Conclusion: the provided sample meets ANSI/AAMI PB70-2012 Level 4.

Signed for and on behalf of SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sama Com

Sara Guo (Account Executive)



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Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

3<sup>™</sup>Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 中国・上海・徐汇区宜山路889号3号楼 邮编: 200233 (86-21) 61402666 f

f (86-21) 64958763 f (86-21) 64958763 www.sgsgroup.com.cn e sgs.china@sgs.com



**Test Report** 

SL52035272103001TX

Date:October 27,2020

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**Test Result** 

Liquid Barrier Performance and Classification of Protective apparel and Drapes Intended for Use in Health Care Facilities

ANSI/AAMI PB70-2012

Section 4.2.1 Water Resistance: Impact Penetration Test

(AATCC 42-2017)

#### As received

Weight of blotter gained (g)	1#	2#	3#	4#	5#
Area A (Critical zone-front)	0.0	0.0	0.0	0.0	0.0
Area B (Critical zone-sleeve)	0.0	0.0	0.0	0.0	0.0
Area C(Front)	1.8	1.5	1.4	1.9	1.9
Area D(Back)	2.3	2.7	2.4	1.9	1.9
Seam between areas A&D	1.2	1.5	1.4	1.7	1.6
Seam between areas C&D	1.4	1.3	1.6	1.3	1.5

#### Remark:

- Level 1: all critical zone components shall have a blotter weight gain of no more than 4.5grams(g)
- Level 2: all critical zone components shall have a blotter weight gain of no more than 1.0 grams(g)
- Level 3: all critical zone components shall have a blotter weight gain of no more than 1.0 grams(g)

#### Section 4.2.1 Water Resistance: Hydrostatic Pressure Test

(AATCC 127-2018; Hydrostatic Head; Rate of increase of water pressure:60mbar/min; temp. of distilled water: 21℃, fabric face side of water)

#### As received

Water Column (cmH <sub>2</sub> O)	1#	2#	3#	4#	5#
Area A (Critical zone-front)	>50.0	>50.0	>50.0	>50.0	>50.0
Area B (Critical zone-sleeve)	>50.0	>50.0	>50.0	>50.0	>50.0
Area C(Front)	11.4	12.3	11.0	12.1	12.6
Area D(Back)	8.57	10.9	10.0	9.49	10.4
Seam between areas A&D	10.1	10.5	12.3	12.0	9.38
Seam between areas C&D	10.7	9.08	11.6	9.89	11.0
Remark:					

- Level 2: all critical zone components shall have a hydrostatic resistance of at least 20cmH<sub>2</sub>O
- Level 3: all critical zone components shall have a hydrostatic resistance of at least 50cmH<sub>2</sub>O



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Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443,

3<sup>rd</sup>Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86–21) 61402666 f (86–21) 64958763 www.sgsgroup.com.cn 中国・上海・徐汇区宜山路889号3号楼 邮编: 200233 t (86–21) 61402666 f (86–21) 64958763 e sgs.china@sgs.com

## 手术衣检测报告(美标,四级)

# Surgical Gown Test Report (SMMS LEVEL 4) SGS

**Test Report** 

SL52035272103001TX

Date:October 27,2020

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Test Report SL52035272103001TX

TX C

Date:October 27,2020

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#### Section 4.2.1 Resistance to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage\*

(ASTM F1671/1671M-2013, Procedure A-no retaining screen)

Test articles Side Tested: Outside

Compatibility Ratio: 1.4 (Chest)/1.4 (Sleeve Seam)/1.7 (Tie Attachment)

Sample	Test Article Number	Pre- Challenge Concentration (PFU/mL)	Post- Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
	1#	3.1 x 10 <sup>8</sup>	2.8 x 10 <sup>8</sup>	<1a	None Seen	Pass
Chest	2#	3.1 x 10 <sup>8</sup>	2.8 x 10 <sup>8</sup>	<1a	None Seen	Pass
	3#	3.1 x 10 <sup>8</sup>	2.8 x 10 <sup>8</sup>	<1a	None Seen	Pass
01	1#	3.1 x 10 <sup>8</sup>	2.8 x 10 <sup>8</sup>	<1a	None Seen	Pass
Sleeve	2#	3.1 x 10 <sup>8</sup>	2.8 x 10 <sup>8</sup>	<1a	None Seen	Pass
Scaiii	3#	3.1 x 10 <sup>8</sup>	2.8 x 10 <sup>8</sup>	<1a	None Seen	Pass
	1#	3.1 x 10 <sup>8</sup>	2.8 x 10 <sup>8</sup>	<1a	None Seen	Pass
Tie Attachment	2#	3.1 x 10 <sup>8</sup>	2.8 x 10 <sup>8</sup>	<1a	None Seen	Pass
Attacimient	3#	3.1 x 10 <sup>8</sup>	2.8 x 10 <sup>8</sup>	<1a	None Seen	Pass
Negative (	Control	3.1 x 10 <sup>8</sup>	2.8 x 10 <sup>8</sup>	<1a	None Seen	Acceptable
Positive C	Control	3.1 x 10 <sup>8</sup>	2.8 x 10 <sup>8</sup>	TNTCb	Yes	Acceptable

#### Remark:

检验检测专用章 Inspection & Testing Services

a A value of <1 PFU/mL is reported for assay plates showing no plaques.

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b TNTC = Plaque forming units (PFUs) were too numerous to count.

Remark: Tests denoted with an \* in this test report have been subcontracted to another ISO 17025 Accredited Laboratory.

# 检验检测专用章 Inspection & Testing Services Standard Co. Little Testing Center-Testing Procedures Standard Co. Little Testing Center-Testing Cente

Barrier performance of each component and final classification commended

	Impact Penetration Test AATCC 42(g)	Hydrostatic Pressure Test AATCC 127(cmH2O)	Resistance to Bacteriophage Phi-X174 ASTM F 1671	Level	Final classification
Area A (Critical zone-front)	0.0	>50.0	Pass	Level 4	
Area B (Critical zone-sleeve)	0.0	>50.0	Pass	Level 4	
Area C(Front)	1.9	11.0	/	Level 1	L ovol 4
Area D(Back)	2.7	8.57	/	Level 1	Level 4
Seam between areas A&D	1.7	9.38	/	Level 1	
Seam between areas C&D	1.6	9.08	/	Level 1	

#### Remark:

- The barrier performance of all critical zone components, including seams and points of attachments, shall be determined;
- The critical zone comprises at least area A and B. The classification of the surgical gown is based on the lower-performing component of the two;
- The back of the surgical gown (area D) may be nonprotective;
- Seams between protective and nonprotective areas have no barrier requirements;
- Seams between two protective areas are required to have at least the barrier performance of the lowerperforming area;
- Level 1: Impact Penetration Test-AATCC 42: ≤4.5g;
- Level 2: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥20cmH<sub>2</sub>O;
- Level 3: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥50cmH<sub>2</sub>O;
- Level 4: Resistance to Bacteriophage Phi-X174-ASTM F 1671: Pass.
- Only test the barrier performance of the sample. Label request, construction and other classed in ANSI/AAMI PB70-2012 is not checked.

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## 手术衣检测报告(美标,四级)

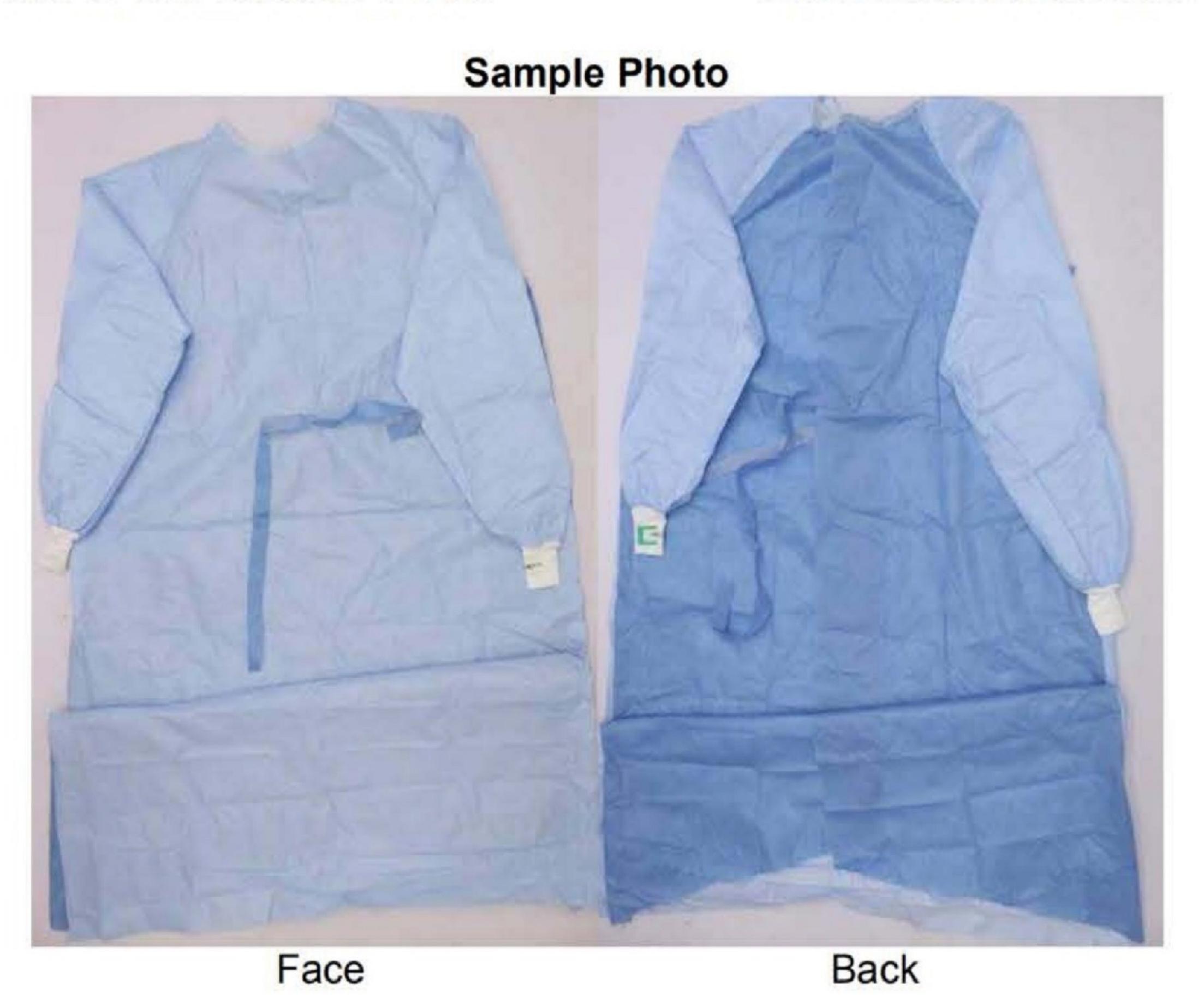
## Surgical Gown Test Report (SMMS LEVEL 4)

Test Report

SL52035272103001TX

Date: October 27,2020

Page 5 of 5



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

\*\*\*End of Report\*\*\*



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手术衣: 规格

# Surgical Gown Packing, certificate of quality



1.尺寸: 58\*36\*53 CM

2.装箱数: 50件/箱

3.净重:12公斤

4.毛重: 13.25 公斤

1.CTN SIZE:58\*36\*53 CM

2.QTY/CTN: 50 PCS

3.N W: 12 KG

4.G W: 13.2 KG