

# Surgical Gown AAMI Level 4

Fabric: SMS + PE 50gsm

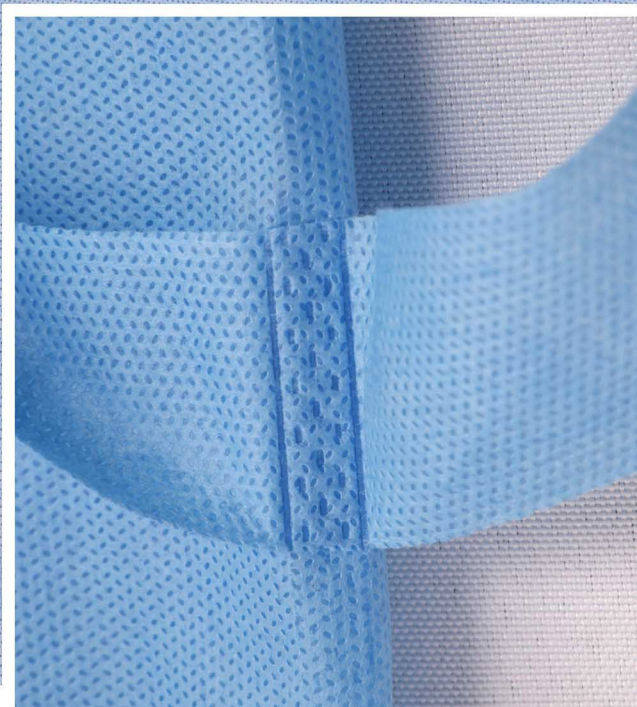
Style: SGW004



***Disposable isolation gown is made of composite non-woven materials, protects workers and patients from contamination with blood, body fluids, secretions. Isolation gown is protective items used by medical personnel to avoid contamination by blood, body fluids and other infections substances, or to protect patients from infection***



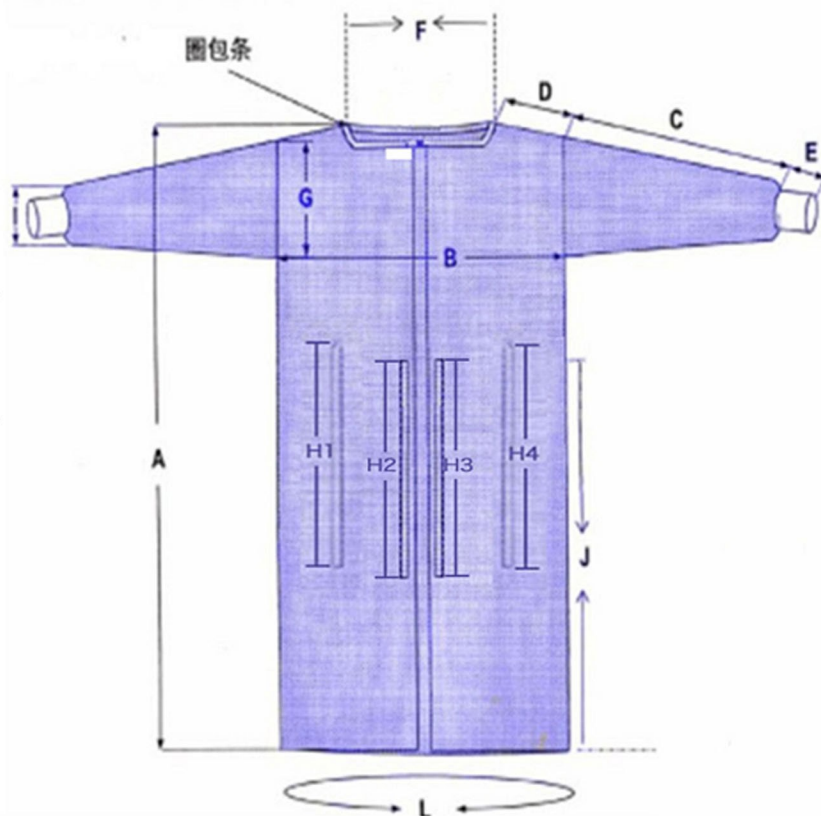






Sugical Gowns Grading			SGW004 SGW001/002/003			
			M	L	XL	XXL
A	Body length from HSP- for tops	肩点身长, 顶量	117.0	120.0	123.0	126.0
B	Chest width below armhole-flat	胸围, 袖笼下1"平量	145.0	150.0	155.0	160.0
C	Sleeve Length-from sleeve seam without rib	袖长-肩缝量不含袖口	57.0	58.0	59.0	60.0
D	shoulder width-one side- neck edge to shoulder seam	单侧肩宽-领边到肩缝	20.0	21.0	22.0	23.0
E	sleeve rib high	袖口螺纹高	7.0	7.0	7.0	7.0
F	Neck width edge to edge	领宽, 边到边	23.5	24.0	24.5	25.0
G	Armhole depth-seam	袖笼深-缝量	32.5	33.0	33.5	34.0
H3	Waistband straps total length	H3 腰带长	70.0	70.0	70.0	70.0
H1/2/4	Waistband straps total length	H1/2/4 腰带长	40.0	40.0	40.0	40.0
L	Bottom width totally	整圈摆围	145.0	150.0	155.0	160.0
I	cuff width-seam	袖口边	14.5	15.0	15.5	16.0
J	Waistband position from bottom	腰带位置-从下摆往上量	64.5	66.5	68.5	70.0

ALL MEASUREMENT BASED ON CM NOT INCH  
 Remark:H1:front panel outside  
 H2/H3:back panel eachside,H4:right back panel inside





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2020/1/19

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## 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

Registration Number:

3006891803

Initial Importer:

N

Facility Name:

CHANGZHOU HOLYMED PRODUCTS CO., LTD  
525 CHANGWU ROAD SOUTH, WUJIN DISTRICT  
CHANGZHOU, Jiangsu, 213167, CHINA

Address:

DUNS Number:

Foreign Trade Zone:

N

Facility URL:

Other Business Trade Name(s):

FDA工厂认证代码

 Edit

### Owner/Operator Information

Owner/Operator Number:

10024103

Contact Name:

XIAOMING WU

Company:

CHANGZHOU HOLYMED PRODUCTS CO., LTD

Address:

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

# 公司于2011年取得FDA认证相关资质

为全球顶级品牌  
提供OEM服务

Review Registration Screen						Review Registration Screen			
D108437	Exempt	FME	GOWN, EXAMINATION	Contract Manufacturer	PRECEPT MEDICAL PRODUCTS, INC. GMAX Industries, Inc.	F	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.
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.	P	COVER, SHOE, OPERATING-ROOM	Contract Manufacturer	OWENS & MINOR DISTRIBUTION, Inc. H-OFFICE
D300777	Exempt	PUI	Drape, surgical, exempt	Contract Manufacturer	CARDINAL HEALTH 200, LLC	IA	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.
D242222	K012984	FYA	GOWN, SURGICAL	Contract Manufacturer	CARDINAL HEALTH 200, LLC				



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## Establishment Registration & Device Listing

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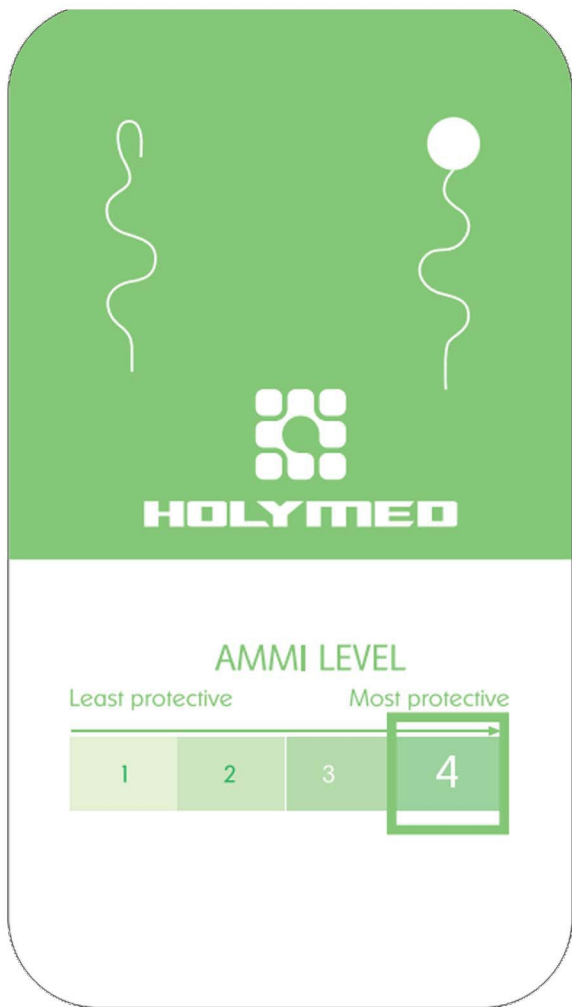
<b>Classification Name:</b>	GOWN, SURGICAL
<b>Product Code:</b>	<a href="#">FYA</a>
<b>Device Class:</b>	2
<b>Regulation Number:</b>	<a href="#">878.4040</a>
<b>Medical Specialty:</b>	General & Plastic Surgery
<b>Registered Establishment Name:</b>	<a href="#">CHANGZHOU HOLYMED PRODUCTS CO., LTD</a>
<b>Registered Establishment Number:</b>	3006891803
<b>Premarket Submission Number:</b>	<a href="#">K170762</a>
<b>Owner/Operator:</b>	<a href="#">CHANGZHOU HOLYMED PRODUCTS CO., LTD</a>
<b>Owner/Operator Number:</b>	10024103
<b>Establishment Operations:</b>	Contract Manufacturer

Page Last Updated: 05/18/2020

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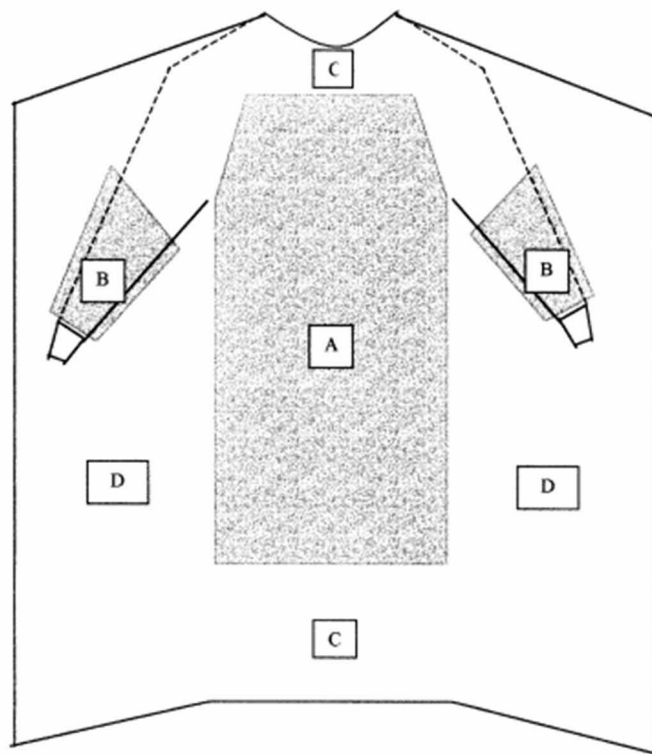
AAMI PB70 Barrier performance	Test Method	Test definition AATCC	Requirement
Level 1	AATCC 42 Impact penetration	AATCC 42 <i>Measures the resistance of fabrics to the liquid penetration of water by impact.</i>	Water impact <4.5g
Level 2	AATCC 42 Impact penetration AATCC 127 Hydrostatic Pressure	AATCC 42 <i>Measures the resistance of fabrics to the liquid penetration of water by impact.</i> AATCC 127 <i>Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.</i>	Spary Impact < 1.0g Hydrostatic Pressure > 20cm
Level 3	AATCC 42 Impact penetration AATCC 127 Hydrostatic Pressure	AATCC 42 <i>Measures the resistance of fabrics to the liquid penetration of water by impact.</i> AATCC 127 <i>Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.</i>	Spary Impact < 1.0g Hydrostatic Pressure > 50cm
Level 4	ASTM F1671 Viral pentration	ASTM F1671 <i>Measures the resistance of fabrics to bloodborne pathogens using viral penetration at 2 psi and ambient pressure</i>	Totally Impervious





**Table B.1—Barrier performance classification of surgical gowns**

Area A (Critical zone—front)	Area B (Critical zone—sleeve)	Area C (Front)	Area D (Back)		Final classification
Level 1, 2, 3, or 4	Level 1	Level 1, 2, 3, or 4	Nonprotective, Level 1, 2, 3, or 4		Level 1
Level 1	Level 1, 2, 3, or 4	Level 1, 2, 3, or 4	Nonprotective, Level 1, 2, 3, or 4		Level 1
Level 2, 3, or 4	Level 2	Level 1, 2, 3, or 4	Nonprotective, Level 1, 2, 3, or 4		Level 2
Level 2	Level 2, 3, or 4	Level 1, 2, 3, or 4	Nonprotective, Level 1, 2, 3, or 4		Level 2
Level 3 or 4	Level 3	Level 1, 2, 3, or 4	Nonprotective, Level 1, 2, 3, or 4		Level 3
Level 3	Level 3 or 4	Level 1, 2, 3, or 4	Nonprotective, Level 1, 2, 3, or 4		Level 3
Level 4	Level 4	Level 1, 2, 3, or 4	Nonprotective, Level 1, 2, 3, or 4		Level 4



**Figure B.1—Example of a gown intended for surgical applications**





# SURGICAL GOWN

Specification: 50 pcs/ carton

Changzhou Holymed Products Co.,Ltd.

## SURGICAL GOWN

ANSI/AAMI BP70-2012  
LEVEL 4



Changzhou Holymed Products Co., Ltd.  
525 Changwu Road, South Wujin District, Changzhou City,  
the People's Republic of China, 213167



CMC Medical Devices & Drugs S.L.  
Horacio Lengo Nº 18, CP 29006, Málaga, Spain



# SURGICAL GOWN

Specification: 50 pcs/ carton

Changzhou Holymed Products Co.,Ltd.

## SURGICAL GOWN

Type: L ■ M ■

QTY:50PIELES

DIM:35\*32\*36CM

N.W:5kg

QW:6KG



2020005001



2020. 05



2022. 05



Changzhou Holymed Products Co., Ltd.  
525 Changwu Road, South Wujin District, Changzhou City,  
the People's Republic of China, 213167



CMC Medical Devices & Drugs S.L.  
Horacio Lengo Nº 18, CP 29006, Málaga, Spain

# HOLYMED Surgical Gown

USA AAMI Level 3 Protection

XXL

## Surgical Gown

The surgical gown is intended to be worn over a scrub suit cover the arms, trunk and upper legs, during a surgical procedure, it is used during surgical procedures to help protect both the patient and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.

## AMMI LEVEL

Least protective Most protective



WED This gown is classified as Level 3 per AAMI Standard PB 70 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.

**Manufactured for:**  
Changzhou HolyMED Products Co., Ltd.  
625 Changze Road, South Wujin District, Changzhou City,  
the People's Republic of China, 213167

202006002

2020.06

2022.06



Made in China

## 合格证 Certification

产品名称: 一次性医用隔离衣  
品牌名称: HOLYMED  
产品规格: 1件/袋  
生产许可证: 202006002  
生产地址: 常州  
生产日期: 2020.06  
有效期至: 2022.06  
执行标准: YYT 0505-2005  
制造商: 常州 HolyMED Products Co., Ltd.  
地址: 常州南门外大街111号  
电话: 0519-88888888  
网址: www.holymed.com.cn  
中国常州 常州 HolyMED Products Co., Ltd.

