

Surgical Gown

CE/FDA/TEST REPORT Approved





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 18 01 83528 008

Manufacturer:

**Henan JoinKona Medical
Products Stock Co., Ltd.**

Xinxing Road
The South of Industry District
LuShan County
467300 PingDingShan, Henan Province
PEOPLE'S REPUBLIC OF CHINA



EC-Representative:

**Shanghai International Holding
Corp. GmbH (Europe)**

Eiffestraße 80
20537 Hamburg
GERMANY

**Product
Category(ies):**

**Surgical Set, Surgical Gown,
Surgical Drape, Tube Cover,
Liquid Collection Pouch,
Warm Blanket and Surgical Hood**

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.:

SH18783EXT01

Valid from:

2018-04-23

Valid until:

2023-04-22

Date, 2018-02-15

Stefan Preiß





Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

HENAN JOINKONA MEDICAL PRODUCTS STOCK CO.,LTD

**Xinxing Road, The South of Industry District, Lushan County,
Pingdingshan, HENAN, 467300, CHINA**

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

Shenzhen CTB Testing Technology Co., Ltd.

Owner/Operator Number: 10062713

Device Listing#: See annex

CTB will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CTB makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. CTB assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, CTB is not affiliated with the U.S. Food and Drug Administration.

CTB



Chief engineer

Issued: March 4, 2020

Expiration Date: December 31, 2020



Fiscal Year 2020 CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10062713

Listing No.	Code	Device Name	Proprietary Names	Activities
D373299	MDM	INSTRUMENT, MANUAL, SURGICAL, GENERAL USE	FEMALE SS 3.5MM PELLET INSERTION TRAY	Manufacturer Contract Manufacturer Contract Sterilizer Repackager/Relabeler Remanufacturer Foreign Exporter
D373300	KDD	Kit, surgical instrument, disposable	Surgical Set	
D373303	FYE	DRESS, SURGICAL	Surgical Gown	
D373304	KME	BEDDING, DISPOSABLE, MEDICAL	Surgical Drape	
D373305	FMW	COVER, MATTRESS (MEDICAL PURPOSES)	Tube Cover	
D373306	KET	FILTERS, CELL COLLECTION, TISSUE PROCESSING	Liquid Collection Pouch	
D373307	FXZ	HELMET, SURGICAL	Warm Blanket and Surgical Hood	

NOT END OF THE ANNEX



Fiscal Year 2020 CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10062713

Listing No.	Code	Device Name	Proprietary Names	Activities
D373308	OEA	Non-surgical isolation gown	Isolation Gown	Manufacturer Contract Manufacturer Contract Sterilizer Repackager/Relabeler Remanufacturer Foreign Exporter
D373309	KPY	Shield, protective, personnel	Protective Coverall	
D373310	IMD	PACK, HOT OR COLD, DISPOSABLE	Dressing Pack	

END OF THE ANNEX



Issued: March 4, 2020
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TEST REPORT

Report No.: SHT16110079-01E

Date: 2016-12-05

Page 1 of 2

The following information of testing sample

Sample Name	Disposable Surgical Gown	Sample No.	T16110079-01
Sample Type	/	Sample Qty.	4pcs
Applicant	Henan Joinkona Medical Products Stock Co.,Ltd		
Address	Xinxing Road, The South of Industry District, LuShan County, PingDingShan City, Henan Province, China		
Sample Received Date	2016-10-28	Testing period	2016-10-28 to 2016-12-01
Test Items	Water resistance, Hydrostatic pressure test		
Test Method	AATCC 42-2013 AATCC 127-2013		
Test Results	Please refer to next page(s)		

*****For more detailed information, please refer to next page(s)*****

Redacted by:

王玉芳

(Yufang Wang)

Reviewed by:

吴涛

(Tao Wu)

Approved by:



(Authorized signatory: Fei Xia)



TEST REPORT

Report No.: S1116 (10079-011) Date: 2016-12-05 Page 2 of 2

Test Result(s):

1. Water resistance

Test Method: AATCC 42-2013

Determinate Standard: According to applicant's requirement

Test Item	Unit	Test Result	Limited Value	Determination
Water resistance	g	0.4	≤1.0	Pass

2. Hydrostatic pressure test

Test Method: AATCC 127-2013

Determinate Standard: According to applicant's requirement

Test Item	Unit	Test Result	Limited Value	Determination
Hydrostatic pressure test	cmH ₂ O	65.2	≥50	Pass

Sample Photo



The End

Remark: The samples provided by the customer, the report test results are only responsible for samples.

The test data is only used for reference, not as a social justice data.

Disposable Surgical Gown

1. Description

Disposable Surgical Gowns are critical items of protective clothing suitable for Operation Room, medical clinics, hospital ward, inspection rooms, laboratories, ICU and CDC sites for important isolation of virus damage.

At Joinkona Medical Company, there is a wide selection of disposable surgical gowns made of SMMS that will certainly serve to protect medical staffs in situations where there are exposure concerns.

2. Advantages to wearing disposable Surgical Gown

Raw Material:

Weight: 35g/M² or 45g/M² SMMS Non-woven Fabrics.

SMMS Performance: Fluid Proof and Anti-Static or Fluid Proof and Anti-Static and Anti-Alcohol and Anti-Blood(AS&AR)

In the healthcare profession, disposable surgical gown play a crucial role in asepsis by reducing the transfer of bacteria from the skin of the medical staff to the air and protect medical staff in operation room. Besides, It will also protect staff members from blood, urine, saline, or other chemicals and bodily fluids during surgical procedures.

Comfortable, Lightweight and Breathable

They are breathable allowing the wearer to be insulated and not overheat.

3. Specifications and Features

Style

One piece of Disposable Surgical Gown

Features

- Single use
- Secure protection (ultrasonic technology)
- Anti-fluid, Anti-alcohol, Anti-blood , Anti-static
- Durable
- Comfortable, Lightweight and Breathable
- Tear-resistant
- Flame retardant



Certificate

- CE
- FDA
- ISO 13485
- EN13795

Standard Surgical Gown



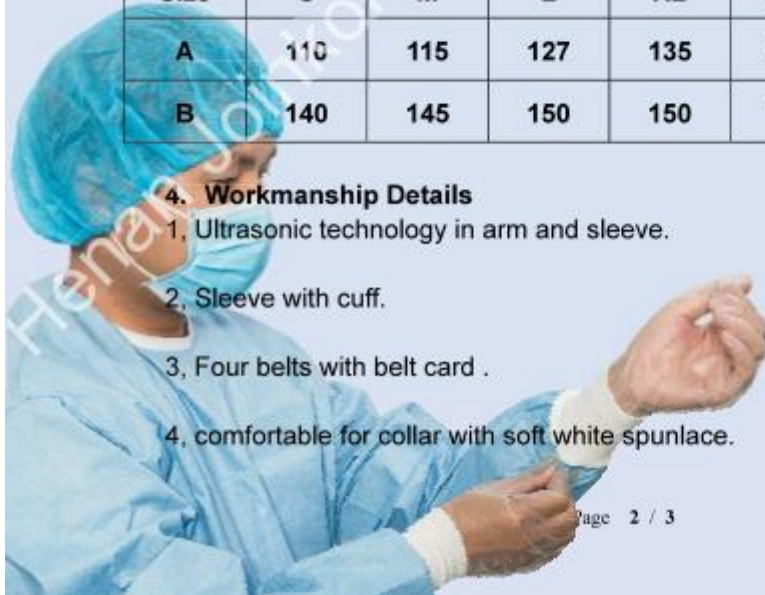
Reinforced Surgical Gown



Surgical Gown Size							Unit:cm
Size	S	M	L	XL	XXL	XXXL	Tolerance
A	110	115	127	135	140	145	±2
B	140	145	150	150	155	160	±2

4. Workmanship Details

- 1, Ultrasonic technology in arm and sleeve.
- 2, Sleeve with cuff.
- 3, Four belts with belt card .
- 4, comfortable for collar with soft white spunlace.



**5. Products Package:
1PC/Sterile Pouch**

35gsm SMMS Standard Surgical Gown and Reinforced Surgical Gown

Products Name	Size	Carton Size	Qty/Carton (pcs)
Standard Surgical Gown	S	50x40x45cm	50
Standard Surgical Gown	M	50x40x45cm	50
Standard Surgical Gown	L	50x40x45cm	50
Standard Surgical Gown	XL	50x40x45cm	50
Standard Surgical Gown	2XL	50x40x45cm	50
Standard Surgical Gown	3XL	50x40x45cm	50
Reinforced Surgical Gown	S	50x40x45cm	50
Reinforced Surgical Gown	M	50x40x45cm	50
Reinforced Surgical Gown	L	50x40x45cm	50
Reinforced Surgical Gown	XL	50x40x45cm	50
Reinforced Surgical Gown	2XL	50x40x45cm	50
Reinforced Surgical Gown	3XL	50x40x45cm	50

45gsm SMMS Standard Surgical Gown and Reinforced Surgical Gown

Products Name	Size	Carton Size	Qty/Carton (pcs)
Standard Surgical Gown	S	50x40x45cm	40
Standard Surgical Gown	M	50x40x45cm	40
Standard Surgical Gown	L	50x40x45cm	40
Standard Surgical Gown	XL	50x40x45cm	40
Standard Surgical Gown	2XL	50x40x45cm	40
Standard Surgical Gown	3XL	50x40x45cm	40
Reinforced Surgical Gown	S	50x40x45cm	40
Reinforced Surgical Gown	M	50x40x45cm	40
Reinforced Surgical Gown	L	50x40x45cm	40
Reinforced Surgical Gown	XL	50x40x45cm	40
Reinforced Surgical Gown	2XL	50x40x45cm	40
Reinforced Surgical Gown	3XL	50x40x45cm	40











