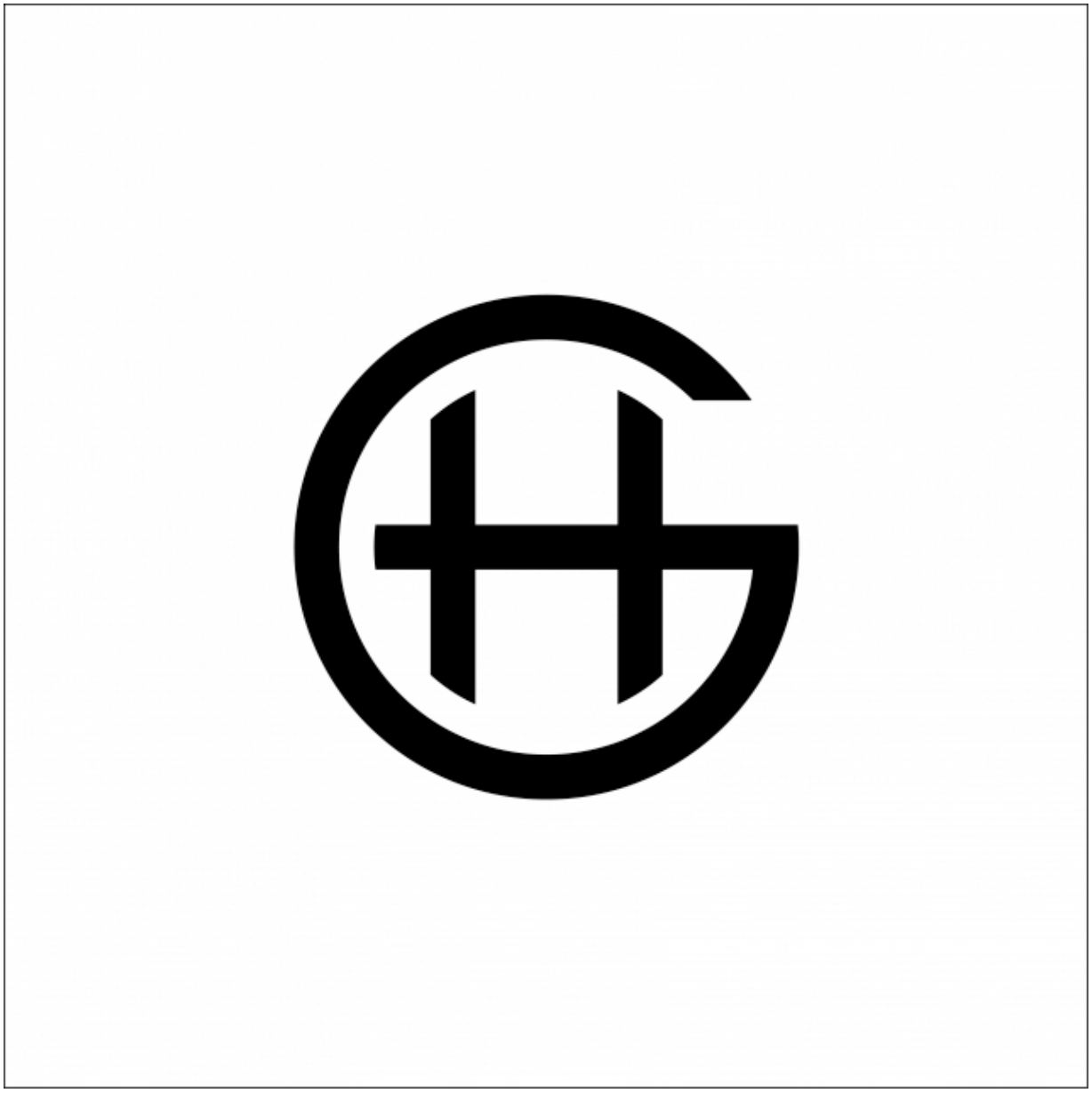


SURGICAL GOWNS

EN 13795

HOLYGROUP 22-25 PORTMAN CLOSE LONDON W1H 6BS
TEL: 020 7846 4095 EMAIL CONTACT@HOLYGROUPUK.COM

PRODUCT DOCUMENTATION

医疗器械生产许可证

许可证编号：豫食药监械生产许20150081号

企业名称：河南洁利康医疗用品有限公司　　生产地址：鲁山县产业集聚区南区新兴路

法定代表人：柯锐　　生产范围：原分类目录：II类：6864医用卫生材料及敷料。※

企业负责人：柯锐

住　　所：鲁山县产业集聚区南区新兴路　　发证部门：河南省药品监督管理局

有效期限：至　2023　年　01　月　26日　　发证日期：　2019　年　09　月　18　日

国家食品药品监督管理总局制

统一社会信用代码
91410400581740735Z

营业执照

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　河南洁利康医疗用品有限公司
类　　型　其他有限责任公司
法定代表人　柯锐
经营范围　医疗器械第II类：6864医用卫生及敷料生产、销售及进出口业务（不包括进口商品的分销业务）。（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）

注册资本　肆仟伍佰万圆整
成立日期　2011年09月06日
营业期限　长期
住　　所　鲁山县产业集聚区南区新兴路

登记机关

2019年04月15日

国家市场监督管理总局监制

PRODUCT DOCUMENTATION

说明书 14x19cm

ARUIKON®
艾锐康

一次性使用手术衣说明书

产品名称：一次性使用手术衣
型号、规格：型号：普通型、加强型；规格：M-S、M、L、XL、XXL；
生产企业：河南洁利康医疗用品有限公司
生产企业地址：鲁山县产业集聚区南区新兴路，邮编：467300
注册企业：河南洁利康医疗用品有限公司
住所：平顶山市鲁山县产业集聚区南区新兴路
售后服务单位：河南洁利康医疗用品有限公司
联系方式：电话：0375-5614666 传真：0375-5614766 质量服务热线：400-0375089
电子信箱：sales@joinkona.com 网址：http://www.joinkona.com
生产许可证：豫食药监械生产许20150081号
注册证编号：豫械注准20172640918
产品技术要求编号：豫械注准20172640918
[产品结构] 本产品普通型由非织造布制作而成，加强型在胸前及双袖追加采用淋膜无纺布制作而成。
[产品性能]
1、一次性使用手术衣的规格及尺寸应符合一次性使用手术衣技术要求2.1中表1的要求。
2、手术衣的外观应色泽均匀、手感柔软、表面平整、无污渍、无破洞等缺陷。
3、袖子缝合处应承受15N拉力，不得出现破损、裂痕、袖子拉脱等现象。
4、手术衣用的非织造布应大于等于35 g/m^2，加强型所使用的淋膜无纺布应大于等于48 g/m^2。
5、手术衣性能中：洁净度、落絮、抗渗水性、胀破强度、拉伸强度、阻微生物穿透应符合YY/0506.2-2016中表1的要求。
6、手术衣经灭菌后无菌。
7、手术衣若采用环氧乙烷灭菌，残留量不大于10ug/g。
8、一次性使用手术衣对皮肤应无刺激与迟发型超敏反应。
[适用范围]适用于医疗单位手术时使用。
[使用方法]
1、根据需求，选择适宜型号的手术衣；
2、打开包装，按无菌操作方式取出手术衣；
3、将手术衣按无菌操作方式穿戴在已消毒过的人员身上；
4、手术衣使用后请小心置入防扎/防穿孔的容器/袋中，按照当地医院或环保要求销毁。
[禁忌症]
1、与本材料过敏者禁用！
[注意事项]
1、本产品由手术医师使用。
2、本产品为一次性使用，使用后的手术衣已经被污染，接触伤口会引发疾病，所以禁止重复使用。
3、禁止二次灭菌。
4、本产品有效期三年，超期请勿使用！
5、包装破损及超过有效期严禁使用，请勿随意丢弃，按医疗垃圾处理。
6、本产品在运输过程中应防晒、防雨淋。
[贮存]：应贮存在相对湿度不超过80%，无腐蚀性气体，阴凉、干燥，通风良好的清洁室内。
[生产日期]：生产批号即生产日期，详见产品最小包装。
[有效期]：三年
说明书编制/修订时间： 2020年01月

② 一次性使用　STERILE EO 环氧乙烷灭菌

说明书14x19cm 80g纸质双色印刷 (Pantone#绿 356C, 黑 Black)

PRODUCT DOCUMENTATION

ICAS
英格尔检测认证集团
ICAS Testing & Certification Group

TEST REPORT

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

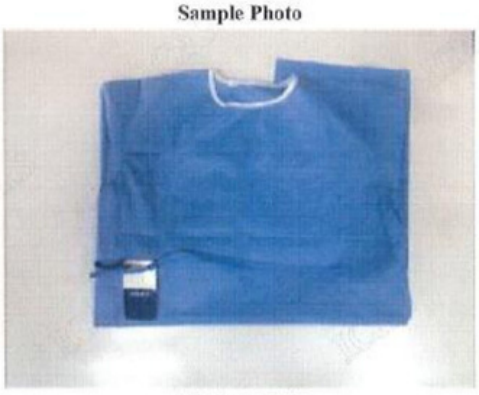
2.Hydrostatic pressure test

Test Method: AATCC 127-2013

Determinate Standard: According to applicant's requirement

Test Item	Unit	Test Result	Limited Value	Determination
Hydrostatic pressure test	cmH_2O	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.

PRODUCT DOCUMENTATION

ICAS
英格尔检测认证集团
ICAS Testing & Certification Group

TEST REPORT

Report No.: SHT16110079-01E Date: 2016-12-05 Page 1of 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)

英格尔检测技术服务（上海）有限公司
ICAS TESTING TECHNOLOGY SERVICES (SHANGHAI) CO. LTD

B 0200361

PRODUCT DOCUMENTATION

ICAS
英格尔检测认证集团
ICAS Testing & Certification Group

关注英格尔检测平台

检 测 报 告

报告编号： SIIT16110079-01　　日期： 2016-12-05　　第2页，共2页

检测结果：

1.拒水性能

检测方法:AATCC 42-2013

判定依据:依据客户提供

检测项目	单位	检测结果	限值	单项判定
拒水性能	g	0.4	≤1.0	符合

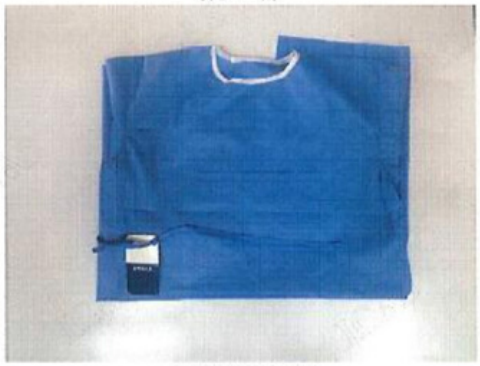
2.耐静水压

检测方法:AATCC 127-2013

判定依据:依据客户提供

检测项目	单位	检测结果	限值	单项判定
耐静水压	cmH_2O	65.2	≥50	符合

样品照片



报告结束

备注:样品由客户提供，此报告检测结果仅对来样负责。

该检测数据仅供测试研究用参考，不做为社会公证性数据。

PRODUCT DOCUMENTATION

ICAS
英格尔检测认证集团
ICAS Testing & Certification Group

关注英格尔检测平台

检 测 报 告

报告编号： SHT16110079-01　　日期： 2016-12-05　　第1页，共2页

以下为测试之样品信息

样品名称	一次性无纺布手术衣	样品编号	T16110079-01
样品型号	/	样品数量	4件
委托单位名称	河南洁利康医疗用品股份有限公司		
委托单位地址	河南省平顶山市鲁山县产业集聚区南区新兴路		
收样日期	2016-10-28	检测周期	2016-10-28 至 2016-12-01
检测项目	拒水性能、耐静水压		
检测方法	AATCC 42-2013　AATCC 127-2013		
检测结果	参见下一页		

******更多详细信息请查阅下页******

编制 王玉芳　　审核 吴涛　　签发

（王玉芳）　　（吴涛）　　（授权签字人：夏飞）

英格尔检测技术服务（上海）有限公司
ICAS TESTING TECHNOLOGY SERVICES (SHANGHAI) CO.,LTD

B 0200359

PRODUCT DOCUMENTATION

中华人民共和国
医疗器械注册变更文件

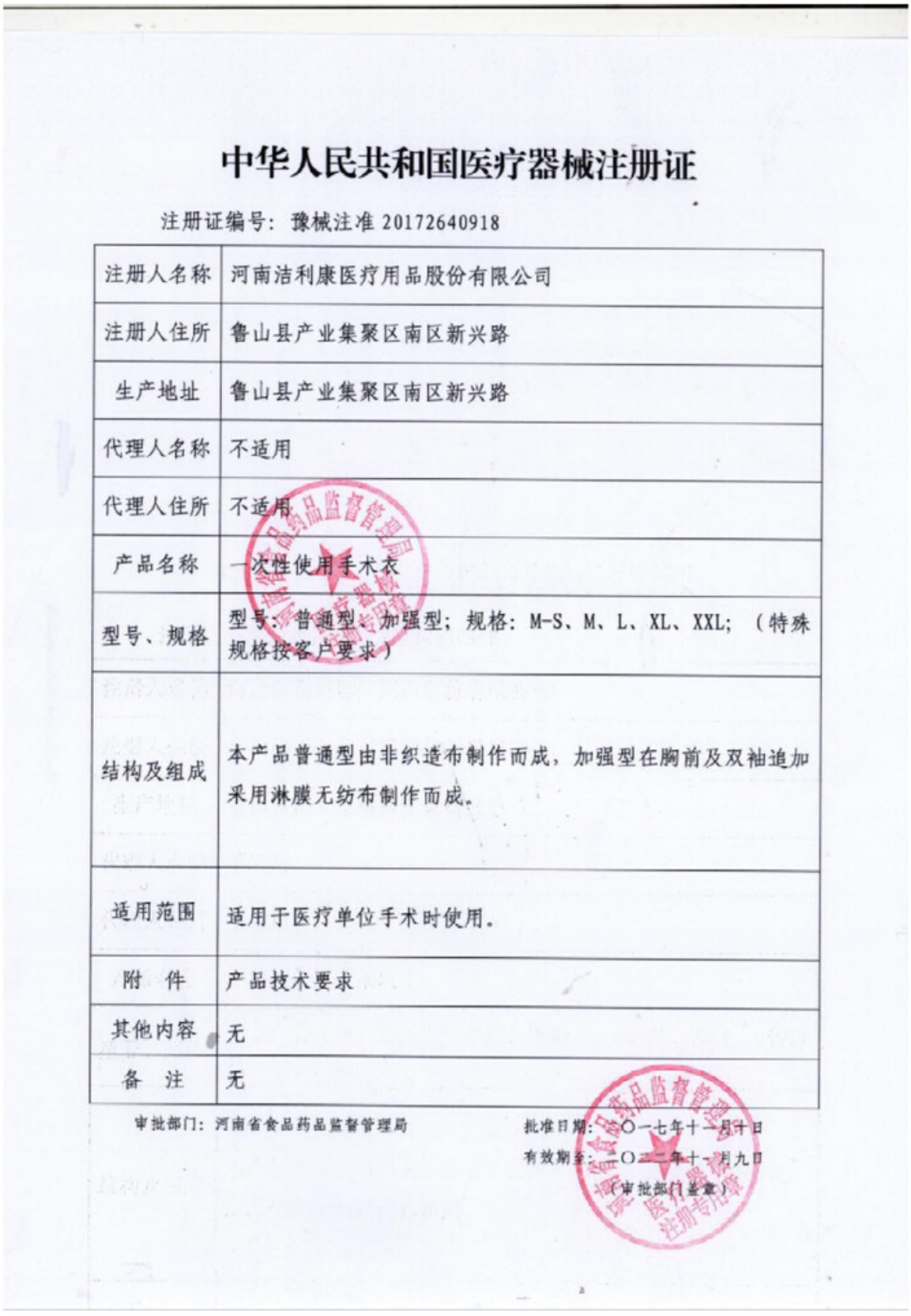
注册证编号：豫械注准20172640918

产品名称	一次性使用手术衣
变更内容	注册人名称由“河南洁利康医疗用品股份有限公司”变更为“河南洁利康医疗用品有限公司”。
备　注	本文件与“一次性使用手术衣（注册证编号：豫械注准20172640918）”注册证共同使用。

审批部门：河南省食品药品监督管理局　　批准日期：二〇一八年四月二十四日

（审批部门盖章）

PRODUCT DOCUMENTATION



中华人民共和国医疗器械注册证

注册证编号：豫械注准 20172640918

注册人名称	河南洁利康医疗用品股份有限公司
注册人住所	鲁山县产业集聚区南区新兴路
生产地址	鲁山县产业集聚区南区新兴路
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用手术衣
型号、规格	型号：普通型、加强型；规格：M-S、M、L、XL、XXL；（特殊规格按客户要求）
结构及组成	本产品普通型由非织造布制作而成，加强型在胸前及双袖追加采用淋膜无纺布制作而成。
适用范围	适用于医疗单位手术时使用。
附　件	产品技术要求
其他内容	无
备　注	无

审批部门：河南省食品药品监督管理局　　批准日期：二〇一七年十一月十日

有效期至：二〇二二年十一月九日

（审批部门盖章）

PRODUCT DOCUMENTATION

医疗器械生产产品登记表

企业名称	河南洁利康医疗用品有限公司
许可证编号	豫食药监械生产许20150081号
许可证有效期限	2019年09月18日 至 2023年01月26日
生产范围	原分类目录：Ⅱ类：6864医用卫生材料及敷料。※
生产范围(新分类目录)	

生产产品列表

序号	产品名称	注册号	登载日期	备注
1	医用一次性防护服	豫械注准20172640921	2018-01-27	
2	手术洞巾	豫械注准20172640920	2018-01-27	
3	一次性使用手术衣	豫械注准20172640918	2018-01-27	
4	手术单	豫械注准20172640919	2018-01-27	
5	手术单组合包	豫械注准20172640922	2018-01-27	
6	一次性使用白内障眼科手术包	豫械注准20162640627	2018-01-27	
7	一次性使用无菌敷料包	豫械注准20172640864	2018-01-27	
8	一次性使用介入包	豫械注准20172640850	2018-01-27	
9	一次性使用剖腹产包	豫械注准20172640974	2018-01-27	
10	一次性使用无菌手术包	豫械注准20182640205	2019-09-18	

PRODUCT DOCUMENTATION

发证部门（公章）：

2019年09月18日

PRODUCT DOCUMENTATION

河南洁利康医疗用品有限公司
Henan JoinKona Medical Products Stock Co.,Ltd

JOINKONA

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/M^2 or 45g/M^2 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

PRODUCT DOCUMENTATION

河南洁利康医疗用品有限公司
Henan JoinKona Medical Products Stock Co.,Ltd

JOINKONA

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

PRODUCT DOCUMENTATION

河南洁利康医疗用品有限公司
Henan JoinKona Medical Products Stock Co.,Ltd

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.

PRODUCT DOCUMENTATION

统一社会信用代码
91410400581740735 2

营业执照

(副 本)(1-1)

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 [redacted]限公司

类　　型 其他有限责任公司

法定代表人 柯锐

经营范围 医疗器械第II类：6864医用卫生及敷料生产、销售及进出口业务（不包括进口商品的分销业务）。
（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）

注册资本 肆仟伍佰万圆整

成立日期 2011年09月06日

营业期限 长期

住　　所 [redacted]

登记机关 平顶山市市场监督管理局

2019 年 04 月 15 日

市场主体应当于每年1月1日至6月30日通过国

国家企业信用信息公示系统网址：
http://10.8.1.130:9080/TopIcis/CertificatePrint.do

国家市场监督管理总局监制
2019-4-15

医疗器械生产许可证

许可证编号：豫食药监械生产许20150081号

企业名称 [redacted]

生产地址：[redacted]

法定代表人：柯锐

生产范围：原分类目录：II类：6864医用卫生材料及敷料。※

企业负责人：柯锐

住　　所：[redacted]路

发证部门：河南省药品监督管理局

有效期限：至 2023 年 01 月 26 日

发证日期：2019 年 09 月 18 日

国家食品药品监督管理总局制

PRODUCT DOCUMENTATION

中华人民共和国
医疗器械注册变更文件

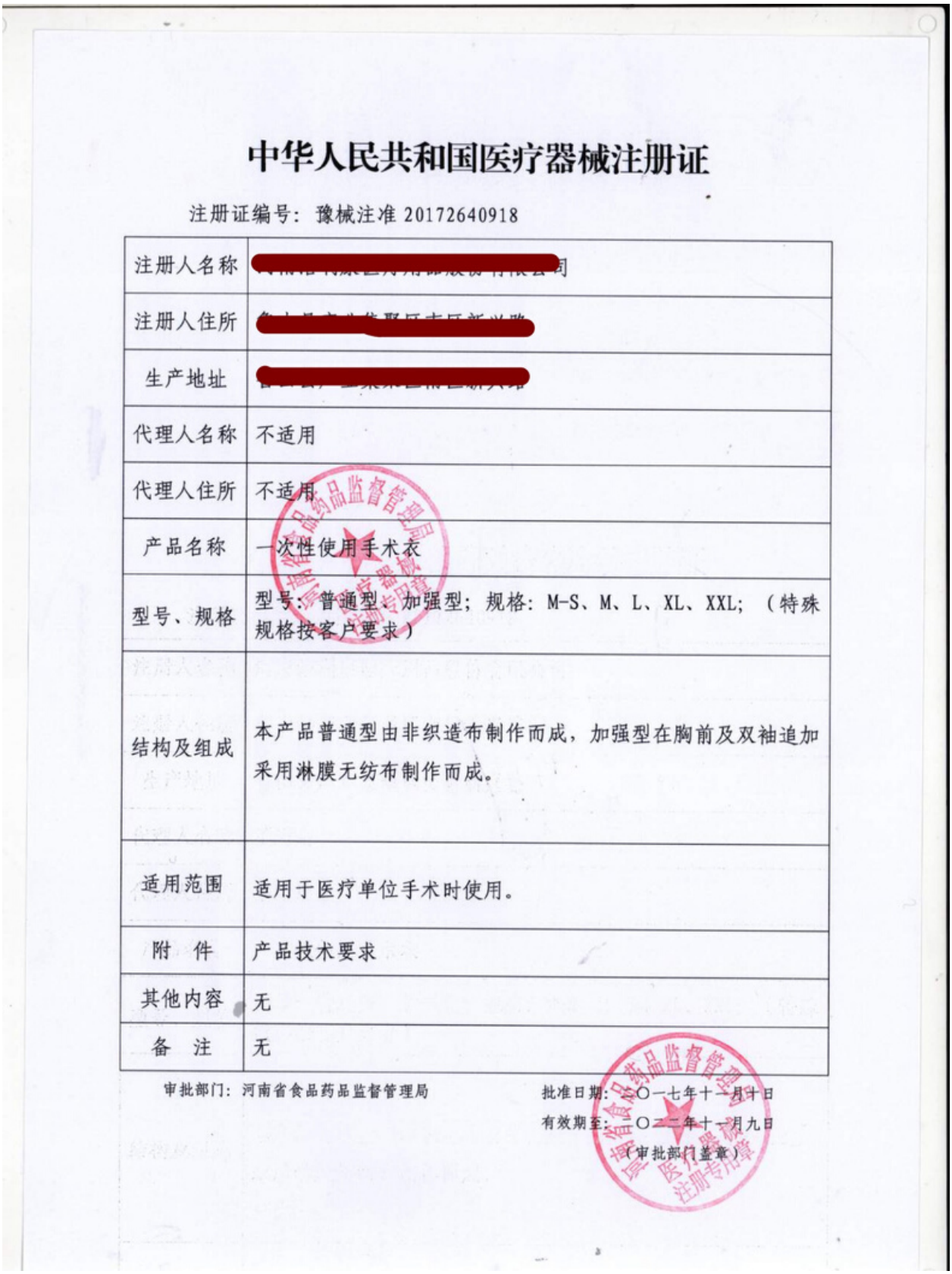
注册证编号：豫械注准20172640918

产品名称	一次性使用手术衣
变更内容	注册人名称由“[redacted]”变更为“[redacted]”。
备　注	本文件与“一次性使用手术衣（注册证编号：豫械注准20172640918）”注册证共同使用。

审批部门：河南省食品药品监督管理局　　批准日期：二〇一八年四月二十四日

（审批部门盖章）

PRODUCT DOCUMENTATION



中华人民共和国医疗器械注册证

注册证编号：豫械注准 20172640918

注册人名称	[redacted]
注册人住所	[redacted]
生产地址	[redacted]
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用手术衣
型号、规格	型号：普通型、加强型；规格：M-S、M、L、XL、XXL；（特殊规格按客户要求）
结构及组成	本产品普通型由非织造布制作而成，加强型在胸前及双袖追加采用淋膜无纺布制作而成。
适用范围	适用于医疗单位手术时使用。
附　件	产品技术要求
其他内容	无
备　注	无

审批部门：河南省食品药品监督管理局

批准日期：二〇一七年十一月十日

有效期至：二〇二二年十一月九日

（审批部门盖章）

PRODUCT DOCUMENTATION

Test Report No.: 721630412-1
Report Date: 10 February 2017

ORIGINAL

SUBJECT	Physical Test
TEST LOCATION	TÜV SÜD China TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	[redacted]
CLIENT ADDRESS	[redacted] Henan Province,China
TEST PERIOD	11-Jan-2017~26-Jan-2017

Prepared By

(Zhu Yichen)
Customer Service

Authorized By

(Spark Shi)
Technical Manager

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

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PRODUCT DOCUMENTATION

Test Report No.: 721630412-1
Report Date: 10 February 2017

ORIGINAL

8. **Test results**

Test Items*		Test Results	Test Methods
Water Resistance Hydrostatic Pressure Test (cmH_2O)	1-Junction of belt	35.8	EN 20811:1992 The rate of water Pressure:10±0.5 cmH_2O/min
	2-Seam area	55.5	
	3-Seam area	54.4	
	4-Non ctitical area	53.0	
	5-Non ctitical area	60.8	

Note1:* denotes this test was carried out by external laboratory assessed as competent.

-END OF THE TEST REPORT-

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PRODUCT DOCUMENTATION

Test Report No.: 721630412-1
Report Date: 10 February 2017

ORIGINAL

Hydrostatic pressure of water resistance

1. **Purpose**

   The purpose of the test was to measure the resistance of a fabric to the penetration of water under hydrostatic pressure.

2. **Sample description was given by the client**

   SMS Surgical Gown Type: XS/S/M/L/XL/XXL/XXXL

3. **References**

   EN 13795:2011
   EN 20811:1992

4. **Apparatus**

   Hydrostatic head tester: Textest FX3000 Hydrostatic Head Tester

5. **Test specimen**

   5.1 As requested by the client, total 5 samples to take specimens from junction of belt,seam area and non ctitical area.
   5.2 Condition the test specimens at(20±2)ºC air at(65±4)% relative humidity for at least 4h before testing.
   5.3 The test surface of the fabric to be exposed to water must to be specified.

6. **Procedure**

   6.1 Verify the water in contact with the specimen is regulate at 20±2ºC.
   6.2 Dry the clamping surface.
   6.3 Clamp the specimen with the surface to be tested facing the water.
   6.4 Select the gradient of (10±0.5)cmH_2O/min,press the start button.
   6.5 Disregarding water droplets that appear within approximately 3mm adjacent to the edge of the specimen clamping ring, record the hydrostatic pressure at the moment water droplets penetrate the fabric in three different places.

7. **Calculation**

   Because the individual hydrostatic pressure values of each specimen were not similar, the individual result of each specimen was used and the mean of the six hydrostatic pressure values did not calculated.

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PRODUCT DOCUMENTATION

Test Report No.: 721630412-2
Report Date: 10 February 2017

ORIGINAL

SUBJECT	**Physical Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	[redacted]
CLIENT ADDRESS	[redacted] Henan Province,China
TEST PERIOD	11-Jan-2017~26-Jan-2017

Prepared By

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Customer Service

Authorized By

(Spark Shi)
Technical Manager

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

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PRODUCT DOCUMENTATION

Test Report No.: 721630412-2
Report Date: 10 February 2017

ORIGINAL

Tensile Strength Test in Dry and Wet State

1. **Purpose**

   For evaluation of tensile strength in dry and wet state.

2. **Sample description was given by the client**

   SMS Surgical Gown Type: XS/S/M/L/XL/XXL/XXXL

3. **References**

   EN 13795:2011+A1:2013
   EN 29073-3:1992

4. **Apparatus**

   Tensile testing machine: CRE type.

5. **Test specimens**

   5.1 As requested by the client, take test specimens from the area of chest.
   5.2 Take each five specimens from the warp(machine) direction and filling(cross) direction for each testing condition.
   5.3 Cut each specimen 50±0.5mm wide and of sufficient length to allow a jaw separation of 200mm.
   5.4 Prior to testing the dry test specimens were conditioned at (20±2)°C and (65±4)% relative humidity for at least 10 hours.
   5.5 For wet test,soak the test specimens for 1h in a solution containing 1g of non-ionic wetting agent per liter of distilled water:Prior to testing the wet test specimens were not conditioned.

6. **Procedure**

   6.1 For dry test
   - 6.1.1 Set the distance between the clamps (gage length) at 200±1mm.
   - 6.1.2 Select the force range of the testing machine for the break to occur between 10 and 90% of full-scale force. Calibrate or verify the testing machine for this range.
   - 6.1.3 Set the testing for a loading rate of 100mm/min unless otherwise specified
   - 6.1.4 Check the jaw face surfaces for flatness and parallelism.
   - 6.1.5 Mount the specimen in the clamp jaws with the previously drawn parallel line adjacent to the side of the upper and lower front, or top, jaws which is nearest this edge, and with approximately the same length of fabric extending beyond the jaw at each end.
   - 6.1.6 Mark across the specimen at the front inner edge of each jaw to check for specimen slippage. When slippage occurs, the mark will move away from the jaw edge.
   - 6.1.7 Operate the machine and break the specimen.
   - 6.1.8 Read the breaking force, and elongation if required, from the mechanism provided for such purpose. Record warp and filling (machine and cross) direction results separately.
   - 6.1.9 If a specimen slips in the jaws, or breaks at the edge of or in the jaws, or if any reason the result falls markedly below the average for the set of specimens, discard the result and take another specimen. Continue this until the required number of acceptable break have been obtained.
   - 6.1.10 If a fabric manifests any slippage in the jaws or if more than 25% of the specimens break at a point within 5mm of the edge of the jaw, the jaw may need to padded or modified.

   6.2 For wet test
   Remove a test sample from the water,placing it on blotting paper to remove excess water.Immediately perform the test according to 6,1.

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PRODUCT DOCUMENTATION

Test Report No.: 721630412-3
Report Date: 10 February 2017

ORIGINAL

SUBJECT	**Physical Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	[redacted]
CLIENT ADDRESS	[redacted] Henan Province,China
TEST PERIOD	11-Jan-2017~26-Jan-2017

Prepared By

(Zhu Yichen)
Customer Service

Authorized By

(Spark Shi)
Technical Manager

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

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PRODUCT DOCUMENTATION

ORIGINAL

7. Calculation

Because the individual tensile strength values of each specimen were not similar, the individual result of each specimen was used and the mean of the five tensile strength values did not calculated.

8. Test results

Test Items*				Test Results	Test Methods
Tensile Strength (N/5cm)	Dry	Length wise	1	97.5	ISO 9073-3:1989 Speed:10±1cm/min
			2	96.5	
			3	100.1	
			4	93.3	
			5	93.9	
		Width wise	1	31.9	
			2	32.8	
			3	32.5	
			4	30.7	
			5	32.2	
	Wet	Length wise	1	96.8	
			2	95.1	
			3	98.5	
			4	98.5	
			5	97.2	
		Width wise	1	32.4	
			2	33.1	
			3	31.1	
			4	31.4	
			5	33.9	

Note1:* denotes this test was carried out by external laboratory assessed as competent.

-END OF THE TEST REPORT-

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PRODUCT DOCUMENTATION

Test Report No.: 721630412-3
Report Date: 10 February 2017

ORIGINAL

Bursting Strength Test in Dry and Wet State

1. **Purpose**

   For evaluation of bursting strength in dry and wet state.

2. **Sample description was given by the client**

   SMS Surgical Gown Type: XS/S/M/L/XL/XXL/XXXL

3. **References**

   EN 13795:2011+A1:2013
   EN ISO 13938-1:1999
   EN 29073-3:1992

4. **Apparatus**

   Mullen Burst Tester: a test area of 7.8 cm^2 (31.6mm diameter), a constant rate of increase in volume of (95±5)cm^3/min.

5. **Test specimen**

   5.1 As requested by the client, total 5 samples to take specimens from junction of belt,seam area and non ctitical area.
   5.2 Cut specimens at least 15cm×15cm.
   5.3 Prior to testing the dry test specimens were conditioned at (20±2)℃ and (65±4)% relative humidity for at least 4 hours.
   5.4 For wet test,soak the test specimens for 1h in a solution containing 1g of non-ionic wetting agent per liter of distilled water,Prior to testing the wet test specimens were not condition.

6. **Procedure**

   6.1 For dry test
   6.1.1 Ensure that the test machine was reset, with the diaphragm flat and the maximum pressure indicator was set to zero.
   6.1.2 Place the test specimen face side up and over the diaphragm so that it lay in a flat tensionless condition, avoiding distortion in its own plane. Clamp it securely in the circular holder, avoiding jaw damage, to prevent slippage during the test. For sleeve seam, put the seam on the central line.
   6.1.3 Apply pressure to the test specimen until the test specimen bursts. Immediately after burst, reverse the apparatus to starting position. Record the bursting pressure.
   6.1.4 Examine the test specimen. If the test specimen bursts close to the edge of the clamping device or the test specimen slipped in the clamp then discard the results and repeat the test with another test position.
   6.1.5 Repeat the procedure 6.1.1 to 6.1.4 for each of the other four test specimens.
   6.2 For wet test
   Remove a test sample from the water, placing it on blotting paper to remove excess water. Immediately perform the test according to 6.1.

7. **Calculation**

   Because the individual bursting pressure values of each specimen were not similar, the individual result of each specimen was used and the mean of the five bursting pressure values did not calculated.

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PRODUCT DOCUMENTATION

Test Report No.: 721630412-3
Report Date: 10 February 2017

ORIGINAL

8. Test results

Test Items*			Test Results	Test Methods
Bursting Strength (kPa)	Dry	1-Junction of belt	275.8	EN ISO 13938-1:1999
		2-Seam area	173.4	
		3-Seam area	173.4	
		4-Non ctitical area	173.4	
		5-Non ctitical area	206.9	
	Wet	1-Junction of belt	344.8	
		2-Seam area	241.3	
		3-Seam area	241.3	
		4-Non ctitical area	173.4	
		5-Non ctitical area	173.4	

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-END OF THE TEST REPORT-

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PRODUCT DOCUMENTATION

Test Report No.: 721630412-4
Report Date: 10 February 2017

ORIGINAL

SUBJECT	**Physical Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	[redacted]
CLIENT ADDRESS	[redacted] Henan Province,China
TEST PERIOD	11-Jan-2017~03-Feb-2017

Prepared By

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Customer Service

Authorized By

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Technical Manager

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

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PRODUCT DOCUMENTATION

Test Report No.: 721630412-4
Report Date: 10 February 2017

ORIGINAL

Linting and Cleanliness of Particulate Matter Test

1. **Purpose**

   For evaluation of linting and cleanliness of particulate matter.

2. **Sample description was given by the client**

   SMS Surgical Gown Type: XS/S/M/L/XL/XXL/XXXL

3. **References**

   EN 13795:2011+A1:2013
   ISO 9073-10:2003

4. **Apparatus**

   4.1 A class 100 cleanroom in accordance with Federal Standard 209E
   4.2 Gelbo Flex Tester
   4.3 Flexing chamber and air collector
   4.4 Particle Counter: eight measurement channels, particle size 0.3~25μm, air flow (28.3±1.4)L/min
   4.5 Gloves, for use in cleanroom
   4.6 Glue

5. **Test specimens**

   5.1 Sample had been sterilized,Take 6 test specimens from the area of the chest and 4 test specimens from the areas of the sleeve seam and cut 4 test specimens from less critical area of the back panel as requested by client.
   5.2 The operator wore gloves and prepared the test specimens under cleanroom conditions.
   5.3 Two sets of seven test specimens were cut, (220±1)mm×(285±1)mm; one set was marked on one face as side A and the other set on the other face as side B. Only five test specimens were used in the test, the other two (top and bottom) test specimens were to protect those in use. The sets of test specimens were free from folds and wrinkles and were kept in cleanroom.

6. **Procedure**

   6.1 The flexing chamber was thoroughly cleaned between each measurement.
   6.2 The particle counter was set for a counting period of 30s and 1s reset time (run mode).
   6.3 With the back panel removed and the flexing unit turned off and with no test specimen in place, two measurements were carried out. The total count of particles ≥0.5μm in 30s was less than 100.
   6.4 The back panel of the chamber was closed with the flexing unit operating but without a test specimen mounted, and after stabilization for ten 30s counting periods, the results were recorded. The results were added to obtain C_0.
   6.5 The circular plates were set in their starting position (188±2)mm apart. A test specimen tube was attached to the circular plates. The flexing chamber was closed. The flexing unit and the particle counter were started concurrently and the flexing unit was run until 10 consecutive periods of 30s had been completed.
   6.6 The flexing unit and the particle counter were stopped, remove the test specimens and clean the flexing chamber.
   6.7 The results for each size classification from the read-out device for the particle counter were recorded.
   6.8 Repeat the procedure 6.3 to 6.7 for all ten test specimens, five from side A and five from side B.

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PRODUCT DOCUMENTATION

Test Report No.: 721630412-6
Report Date: 10 February 2017

ORIGINAL

SUBJECT	Microbiological Test
TEST LOCATION	TÜV SÜD China TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	[redacted]
CLIENT ADDRESS	[redacted] Henan Province,China
TEST PERIOD	11-Jan-2017~26-Jan-2017

Prepared By

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Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

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PRODUCT DOCUMENTATION

ORIGINAL

Resistance To Wet Microbial Penetration Test

1. **Purpose**

   For evaluation of resistance to wet bacterial penetration.

2. **Sample description was given by the client**

   SMS Surgical Gown Type: XS/S/M/L/XL/XXL/XXXL

3. **References**

   EN 13795:2011+A1:2013
   EN ISO 22610:2006

4. **Apparatus and materials**

   4.1 *Staphylococcus aureus* ATCC 29213
   4.2 Peptone water
   4.3 Nurient agar plates (14cm diameter)
   4.4 Carrier material: PU film (30μm thickness)
   4.5 Covering material: HDPE film
   4.6 Cylindrical body
   4.7 RULLA 2 Wet-Penetration-Test
   4.8 Oven

5. **Test specimen**

   5.1 As requested by the client, take the test specimens from the fabric,the tie and the seam of sample.
   5.2 Sample had been sterilized. Cut a test specimens 25cm×25cm under aseptic conditions.

6. **Procedure**

   6.1 Preparation
      6.1.1 Six petri dishes, 14cm in diameter, were filled with nutrient agar to (3±0.2)mm from the brim.
      6.1.2 Preparation of donor: Evenly distribute 1.0mL of the *Staphylococcus aureus* suspension with a concentration of 1.7×10^4 CFU/mL over an area corresponding to the lid of the agar plate of the carrier. Dry the donor at 56°C for approximately 30min.
   6.2 Place the first agar plate on the turntable.
   6.3 Put a test specimen on the ring, and put the donor, contaminated side down, on the specimen. Cover the PU film with a piece of HDPE film, then push the outer ring down firmly so that the three materials were securely held between the two rings.
   6.4 With the materials slightly slack, place the ring on the first lidless agar plate, such that the steel ring hangs freely outside the turntable. Apply the finger to the HDPE film just inside the brim in such a way that the test specimen comes into contact with the agar surface. Run the test as described for 15min with a finger pressure of 3N.
   6.5 After 15min, remove the ring and the assemblage immediately and retain.
   6.6 Remove the first agar plate from the turntable and seal it with its lid. Immediately put the second agar plate on the turntable, together with the retained ring assemblage.
   6.7 Perform the above-mentioned procedure on the same test assemblage using the next four plates.

PRODUCT DOCUMENTATION

ORIGINAL

8. Test results

Test Items*			Test Results					Test Methods
			1	2	3	4	5	
Resistance to Microbial Penetration-Wet	Test time \(CFU)	15 min	427	411	569	694	431	EN ISO 22610:2006
		30 min	266	314	543	460	557	
		45 min	184	297	398	381	364	
		60 min	93	139	193	229	270	
		75 min	142	121	148	185	219	
		Donor	205	269	304	225	247	
	Barrier Index, I_B	Individual	2.903	3.034	2.870	2.736	3.014	
		Mean	2.911					

Note1: Suspension Conc.:1.7×10^4 CFU/ml.

Note2: Sampling location :(1)Front chest with Front tie
(2)(4)Sleeve seam
(3)Front chest(fabric)

Note2:* denotes this test was carried out by external laboratory assessed as competent.

-END OF THE TEST REPORT-

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6.8 When five plates have been tested, remove and discard the donor, turn the test specimen upside down and cover it with the HDPE film.
6.9 Run the sixth plate for 15min on the first replicate to complete the test run.
6.10 Repeat the procedure 6.2 to 6.9 for each of the other four test specimen, using a freshly prepared donor with each test specimen.
6.11 If liquid had accumulated on the agar surface, dry the plate(s) on a clean beach and incubate the six agar plates with their lids on for 48h at 35°C.
6.12 Count the colonies of *Staphylococcus aureus* on each plate. Disregard the count in the area with a radius of 15mm around the centre of the plate.

7. Calculation

7.1 The estimated bacterial challenge, T, was calculated as follows:

$T = Z+X_1+X_2+X_3+X_4+X_5$

Where

Z — is the number of colonies from the top side of the test specimen that are left over after the five agar plates have been run, measure on the sixth agar plate (plate 6);

$X_1,\cdots,X_5$ — are the numbers of colonies on the 5 plates in one replicate test, using the same test specimen and donor.

7.2 The cumulative penetration ratio of plates 1 to 5, $R_{CUM1},\cdots,R_{CUM5}$, was calculated as follows:

$$R_{CUM1}=\frac{X1}{T}$$

$$R_{CUM2}=\frac{(X1+X2)}{T}$$

$$R_{CUM3}=\frac{(X1+X2+X3)}{T}$$

$$R_{CUM4}=\frac{(X1+X2+X3+X4)}{T}$$

$$R_{CUM5}=\frac{(X1+X2+X3+X4+X5)}{T}$$

7.3 Barrier index, I_B, was calculated as follows:

$I_B=6-(R_{CUM1}+R_{CUM2}+R_{CUM3}+R_{CUM4}+R_{CUM5})$

Chemical/Microbiology Laboratory:
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PRODUCT DOCUMENTATION

Test Report No.: 721630412-7
Report Date: 10 February 2017

ORIGINAL

Cleanliness of Microbial Test

1. **Purpose**

   For determination of a population of microorganisms (Facultative, non-fastidious, aerobic bacteria; Yeasts and moulds).

2. **Sample description was given by the client**

   SMS Surgical Gown Type: XS/S/M/L/XL/XXL/XXXL

3. **References**

   EN 13795:2011+A1:2013
   EN ISO 11737-1:2006

4. **Apparatus and materials**

   4.1 Stomacher (BagMixer400)
   4.2 Stomacher bag
   4.3 Eluent:Buffered peptone water+0.05% Tween 80
   4.4 Tryptone soya agar (TSA)
   4.5 Sabouraud dextrose agar (SDA)
   4.6 Filtration equipment
   4.7 Sterilized membrane (0.45μm)

5. **Test specimen**

   5.1 Take a total of 6 test specimens. Cut a test specimen 100mm×100mm under aseptic condition.

6. **Procedure**

   6.1 Bioburden test
   - 6.1.1 Put a test specimen into small pieces,and enclose in a stomacher bag under aseptic conditions.
   - 6.1.2 Pour into 100mL buffered peptone water(eluent) and process 3min in a stomacher individually by highest speed. Filtrate the eluent by membrane filter.
   - 6.1.3 Individually, membrane filters were put on TSA and incubated 5d at 35°C for Facultative, non-fastidious, aerobic bacteria, and on SDA 7d at 25°C for Yeasts and moulds.
   - 6.1.4 Repetitive treatment as bioburden test four times.
   - 6.1.5 Finally, coating the surface of test specimens with molten medium (TSA and SDA), allowing the media to solidify and exposing the test specimens to specified culture conditions
   - 6.1.6 Take 3 test specimens for Facultative, non-fastidious, aerobic bacteria. And take 3 test specimens for Yeasts and moulds

   6.2 The colonies formed on incubation were counted.

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PRODUCT DOCUMENTATION

Test Report No.: 721630412-7
Report Date: 10 February 2017

ORIGINAL

SUBJECT	Microbiological Test
TEST LOCATION	TÜV SÜD China TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	[redacted]
CLIENT ADDRESS	[redacted] Henan Province,China
TEST PERIOD	11-Jan-2017~03-Feb-2017

Prepared By

(Zhu Yichen)
Customer Service

Authorized By

(Spark Shi)
Technical Manager

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

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PRODUCT DOCUMENTATION

ORIGINAL

7. Calculation

Treatment	TSA	SDA
1	12	19
2	2	2
3	0	6
4	0	0
Agar overlay	0	0
Total colony count	14	27

7.1 Recovery efficiency (%)= $\frac{\text{Number recovered by first treatment}}{\text{Total number recovered}} \times 100$

7.2 Correction factor= $\frac{100}{\text{Recovery efficiency (\%)}}$

Items	B	F
Recovery efficiency (%)	85.7	70.4
Correction factor	1.2	1.4

Note: B= Facultative, non-fastidious, aerobic bacteria
F= Yeasts and moulds

7.3 Bioburden=Number recovered by first treatment × Correction Factor

8. Test results

Test Items*	Test Results			Test Methods
	Specimen 1	Specimen 2	Specimen 3	
Facultative, non-fastidious, aerobic bacteria (CFU/100cm²)	14.7	16.4	15.4	EN ISO 11737-1:2006 B.2.2.1/B.4.2
Yeasts and moulds (CFU/100cm²)	18.5	9.4	2.8	

Note1:* denotes this test was carried out by external laboratory assessed as competent.

-END OF THE TEST REPORT-

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PRODUCT DOCUMENTATION

CMA
2012160647S
有效期2015年2月6日

No. 注20130690

河南省医疗器械检验所

检验报告

产品名称：一次性使用手术衣

检验类别：注册检验

委托方：[redacted]

PRODUCT DOCUMENTATION

河 南 省 医 疗 器 械 检 验 所

检 验 报 告 首 页

报告编号：注20130690　　共 4 页 第 1 页

样品名称	一次性使用手术衣 送样（√）　抽样（　）	样品数量	45包
		规格型号	普抗SMS加强型手术衣 XL号
委托方	[redacted]	商　标	洁利康
委托方地址	[redacted]	样品批号	13060603
生产单位	[redacted]	生产日期	/
受检单位	[redacted]	有 效 期	三年
抽样单位	/	检验类别	注册检验
抽样基数	/	样品状态	正 常
抽样日期	/	收样日期	2013.07.12
抽样地点	/	检验地点	本检验所试验室
抽样单编号	/	检验日期	2013.08.09—2013.10.09
检验项目	全项目		
检验依据	YZB/豫0217-2013《一次性使用手术衣》		
检验结论	被检样品符合YZB/豫0217-2013《一次性使用手术衣》标准要求。 签发日期：2013.10.9		
备　注	1）报告中的“----”表示此项不适用，报告中“/”表示此项空白。 2）附件：拟申请注册医疗器械产品标准预评价意见表。		

报告批准：　　报告审核：　　检　验：张娟丽

PRODUCT DOCUMENTATION

河南省医疗器械检验所

检验报告

报告编号：注20130690

一次性使用手术衣

检验项目	标准条款	标准要求	检验结果	单项结论
制作	3.1	手术衣分普通型及加强型两种型号，其中普通型为非织造布制作而成，加强型在胸前及双袖追加采用淋膜无纺布制作而成	加强型	合格
规格尺寸	3.2	手术衣的规格及尺寸应符合表1的规定（身长：138cm±2cm，胸围：72.5cm±2cm）	身长：138cm，胸围：72.8cm	合格
外观	3.3	手术衣应色泽均匀、手感柔软、表面平整、无污渍、破洞等缺陷	符合要求	合格
抗拉能力	3.4	手术衣袖子缝合处应能承受15N拉力，不得出现破损、裂痕、袖子拉脱等现象	符合要求	合格
非织造布、无纺布规格	3.5	手术衣用的非织造布应大于等于为35g/m²，加强型所使用的淋膜无纺布应大于等于为48g/m²	手术衣用的非织造布：44g/m²，加强型所使用的淋膜无纺布：49g/m²	合格
阻微生物穿透，干态	3.6	产品非关键区域$\log_{10}$ CFU应≤2	符合要求	合格
阻微生物穿透，湿态		产品关键区域I_a应≥2.8	符合要求	合格
洁净度，微生物		产品关键区域应≤2c $\log_{10}$(CFU/dm²)，，产品非关键区域应≤2c $\log_{10}$(CFU/dm²)	——	——
洁净度，微粒物质		产品关键区域应≤3.5 IPM，产品非关键区域应≤3.5 IPM	产品关键区域A面IPM：2.1，B面IPM：1.1；产品非关键区域A面IPM：2.6，B面IPM：2.4	合格
落絮		产品关键区域应≤4.0 $\log_{10}$（落絮计数），产品非关键区域应≤4.0 $\log_{10}$（落絮计数）	产品关键区域A面落絮系数：3.8，B面落絮系数：3.9；产品非关键区域A面落絮系数：3.7，B面落絮系数：3.9	合格
抗渗水性		产品关键区域应≥20cmH_2O，产品非关键区域应≥10cmH_2O	产品关键区域：30cmH_2O，产品非关键区域应：32cmH_2O	合格

PRODUCT DOCUMENTATION

河南省医疗器械检验所

检验报告照片页

报告编号：注20130690　　共 4 页 第 4 页

照片和说明

样品描述

/

型号规格或其他说明

产品标示型号规格：　普抗SMS加强型手术衣XL号。

PRODUCT DOCUMENTATION

河南省医疗器械检验所

检验报告

报告编号：注20130690

一次性使用手术衣

检验项目	标准条款	标准要求	检验结果	单项结论
胀破强度，干态	3.6	产品关键区域应≥40kPa，产品非关键区域应≥40kPa	产品关键区域：41kPa，产品非关键区域：41kPa	合格
胀破强度，湿态		产品关键区域应≥40kPa	产品关键区域：41kPa	合格
拉伸强度，干态		产品关键区域应≥20N，产品非关键区域应≥20N	产品关键区域纵向：94N，横向：62N，产品非关键区域纵向：96N，横向：59N	合格
拉伸强度，湿态		产品关键区域应≥20N	纵向：95N，横向：56N	合格
无菌	3.7	手术衣经灭菌后无菌	无菌生长	合格
环氧乙烷残留量	3.8	手术衣若采用环氧乙烷灭菌，残留量不大于10μg/g	未检出环氧乙烷	合格
刺激	3.9	一次性使用手术衣对皮肤应无刺激	符合要求	合格
致敏		一次性使用手术衣对皮肤应无迟发型超敏反应	符合要求	合格
备注：				

PRODUCT DOCUMENTATION

附件

拟申请注册医疗器械产品标准预评价意见表

检测报告编号：注20130690　　共 1 页　第 1 页

一、产品标准引用现行强制性国家标准、行业标准方面存在的问题：

无

二、产品标准引用推荐性国家标准、行业标准方面存在的问题：

无

三、产品标准中试验方法方面存在的问题：

无

四、其它需要说明的问题：

无

五、综合评价意见：

■ 产品标准基本满足相关标准的要求

□ 产品标准在以下方面需要进一步补充、完善：

河南省医疗器械检验所 检验报告专用章

PRODUCT DOCUMENTATION