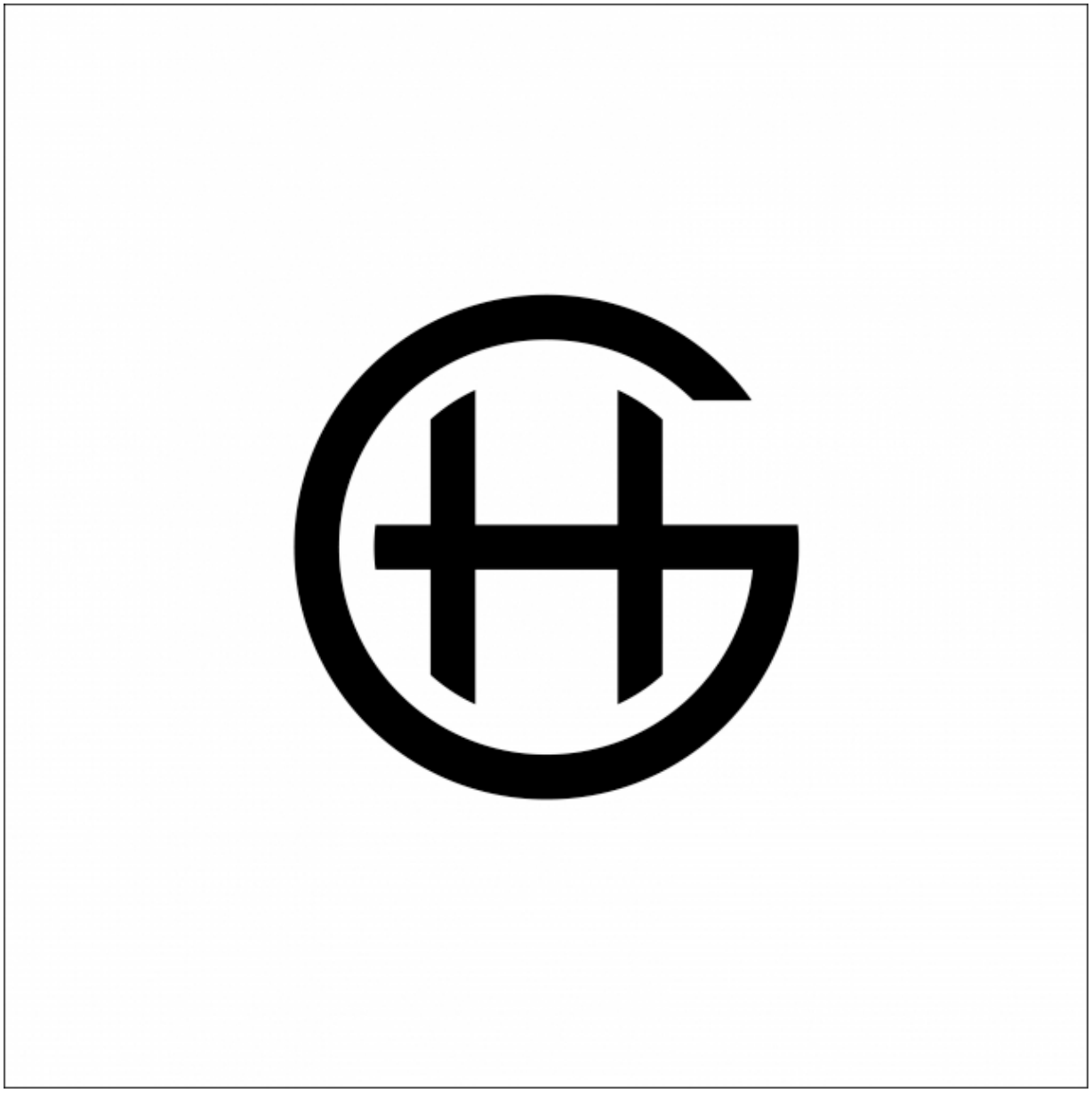


SURGICAL GOWNS

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）

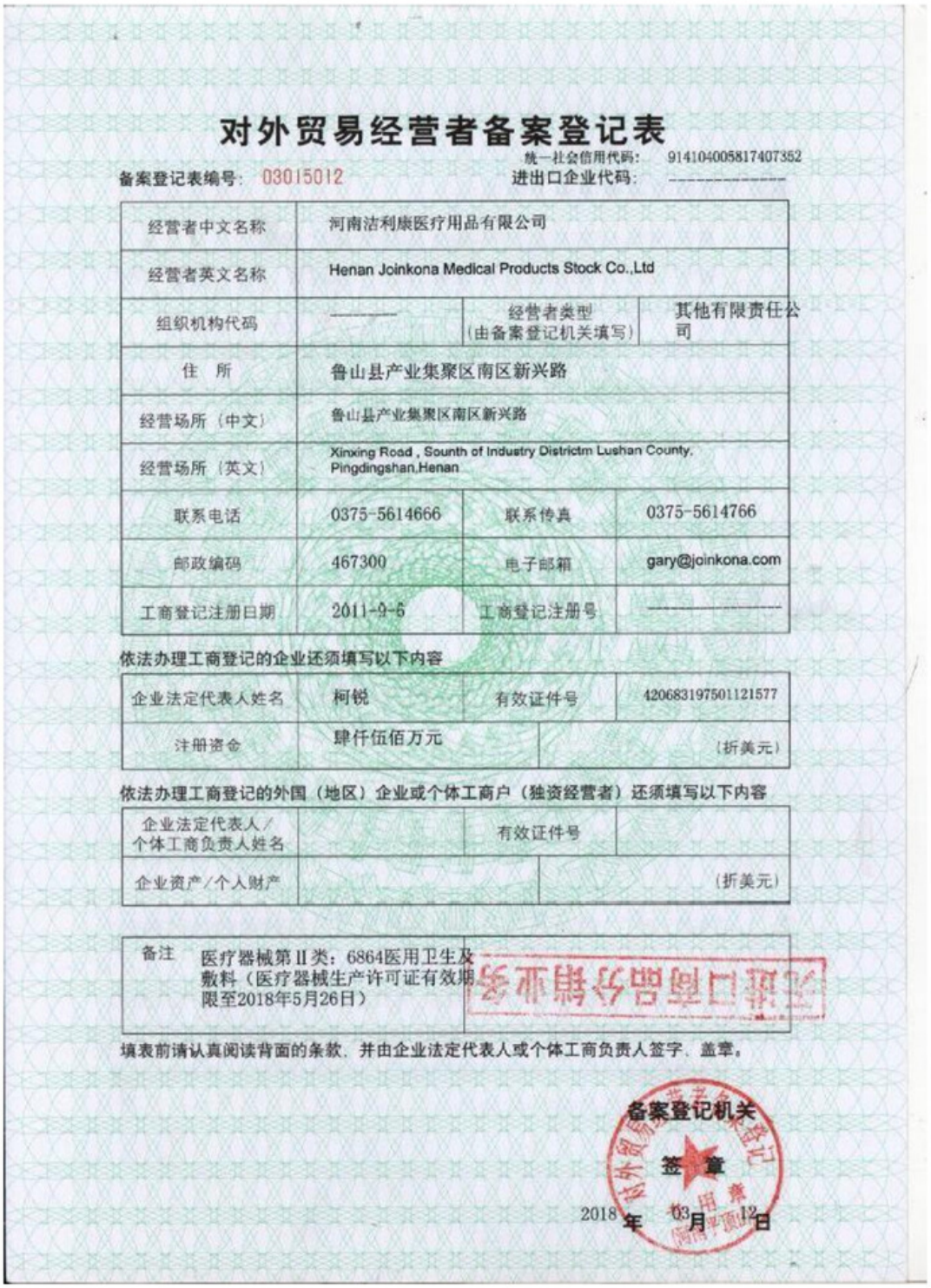
注册资本　肆仟伍佰万圆整
成立日期　2011年09月06日
营业期限　长期
住　　所　鲁山县产业集聚区南区新兴路

登记机关

2019年04月15日

国家市场监督管理总局监制

PRODUCT DOCUMENTATION



对外贸易经营者备案登记表

统一社会信用代码：91410400581740735 2

备案登记表编号：03015012　　进出口企业代码：----------

经营者中文名称	河南洁利康医疗用品有限公司		
经营者英文名称	Henan Joinkona Medical Products Stock Co.,Ltd		
组织机构代码	----------	经营者类型（由备案登记机关填写）	其他有限责任公司
住　所	鲁山县产业集聚区南区新兴路		
经营场所（中文）	鲁山县产业集聚区南区新兴路		
经营场所（英文）	Xinxing Road , Sounth of Industry Districtm Lushan County, Pingdingshan,Henan		
联系电话	0375-5614666	联系传真	0375-5614766
邮政编码	467300	电子邮箱	gary@joinkona.com
工商登记注册日期	2011-9-5	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	柯锐	有效证件号	420683197501121577
注册资金	肆仟伍佰万元		（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	医疗器械第Ⅱ类：6864医用卫生及敷料（医疗器械生产许可证有效期限至2018年5月26日）

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。

备案登记机关

签　章

2018 年 03 月 12 日

PRODUCT DOCUMENTATION

出入境检验检疫企业备案表

编　　号： 18040311251500000381
备案类别： 进出口企业　代理报检企业　快件运营企业　**备案号码：** 4101601351

企业名称	中文	河南洁利康医疗用品有限公司	
	英文	HENAN JOINKONA MEDICAL PRODUCTS STOCK CO.,LTD	
住　　所	河南省平顶山市鲁山县产业集聚区南区新兴路		
经营场所	河南省平顶山市鲁山县产业集聚区南区新兴路		
企业性质	私营企业	企业类别	有自营权的生产企业
统一社会信用代码	914104005817407352	营业执照号	410423000009340
组织机构代码	581740735	行政区划	平顶山市鲁山县
法定代表人/负责人	柯锐	有效证件号	420683**********1577
联系人	徐艳培	联系电话	15638655611
电子邮箱	robin@joinkona.com		

快件运营企业备案还须填写以下内容

快递业务经营许可证号	
经营范围	

报检专用章印模：（另附页）
填表前请认真阅读背面的条款，并由企业法定代表人/负责人签字、盖章。

备案机构（签章）
2018 年 4 月 18 日

中华人民共和国河南出入境检验检疫局 报检企业管理专用章 002

PRODUCT DOCUMENTATION

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

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, Protective Coverall, 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

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

A1 / 07.17

PRODUCT DOCUMENTATION

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

TÜV SÜD Product Service

Supplement to Quality System Certificate

No. SUP 083528 0012 Rev. 00

This supplement is only valid in conjunction with the main certificate: **Q8 083528 0011 Rev. 00**

Certificate Holder:

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

Facility(ies):

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

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: SH1978307

Dated: 2019-02-20

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: 2019-04-01

I. Preiß

Stefan Preiß

A4 / 07.17

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

TÜV®

PRODUCT DOCUMENTATION

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

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

TÜV SÜD Product Service

Certificate

No. Q8 083528 0011 Rev. 00

Holder of Certificate: **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

Facility(ies): **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

Certification Mark:

Scope of Certificate: **ETO Sterilization for Medical Device**

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). See also notes overleaf.

Report No.: SH1978307

Valid from: 2019-04-01
Valid until: 2022-03-31

Date, 2019-04-01

Stefan Preiß

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

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A4 / 07.17

PRODUCT DOCUMENTATION

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

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

Facility(ies):

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

PRODUCT DOCUMENTATION

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 FDA

CTB TESTING TECHNOLOGY CTB

Chief engineer

Issued: March 4, 2020

Expiration Date: December 31, 2020

PRODUCT DOCUMENTATION

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

PRODUCT DOCUMENTATION

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

Chief engineer

Issued: March 4, 2020

Expiration Date: December 31, 2020

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

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

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

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:

[redacted]
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, Protective Coverall, 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

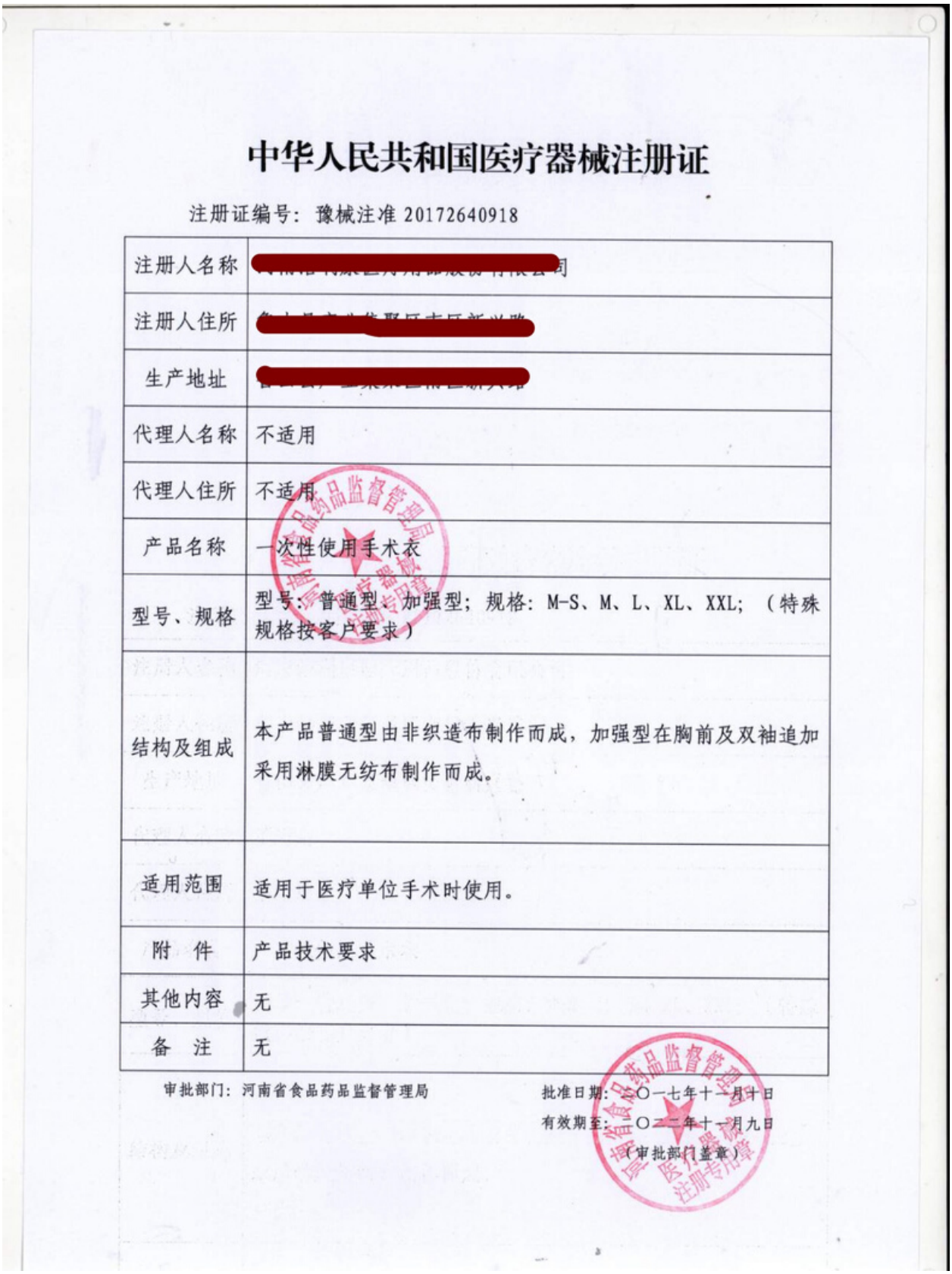
Date, 2018-02-15

Stefan Preiß

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

A1 / 07.17

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

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

TÜV SÜD 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

Facility(ies): [redacted] Ltd.
trict,
n
NA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

A1 / 07.17

PRODUCT DOCUMENTATION

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

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

TÜV SÜD
Product Service

Certificate

No. Q8 083528 0011 Rev. 00

Holder of Certificate: [redacted]
Xinxing Road
[redacted] Province
[redacted]

Facility(ies): **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

Certification Mark:

Scope of Certificate: **ETO Sterilization for Medical Device**

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). See also notes overleaf.

Report No.: SH1978307

Valid from: 2019-04-01
Valid until: 2022-03-31

Date, 2019-04-01

Stefan Preiß

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A4 / 07.17

PRODUCT DOCUMENTATION

TÜV SÜD Product Service

Supplement to Quality System Certificate

No. SUP 083528 0012 Rev. 00

This supplement is only valid in conjunction with the main certificate: **Q8 083528 0011 Rev. 00**

Certificate Holder:

[redacted]
Xinxing Road
[redacted]
[redacted]ince
PE[redacted]NA

Facility(ies):

[redacted]d.
Xi[redacted]
4[redacted]
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: SH1978307

Dated: 2019-02-20

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: 2019-04-01

Stefan Preiß

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

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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.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

PRODUCT DOCUMENTATION

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

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

TÜV SÜD
Product Service

Certificate

No. Q6 083528 0010 Rev. 00

Holder of Certificate: [redacted]
Xinxing Road
[redacted]rict
LuShan County
[redacted]enan Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): [redacted]
Xi[redacted]
467300 PingDi[redacted]EPUBLIC
OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Surgical Set, Surgical Gown, Surgical Drape, Tube Cover, Liquid Collection Pouch, Protective Gown, Warm Blanket and Surgical Hood**

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). See also notes overleaf.

Report No.: SH1978307

Valid from: 2019-04-01
Valid until: 2022-03-31

Date, 2019-04-01

Stefan Preiß

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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]