

WELCOME TO HUBEI HAIXIN

湖北海興衛生用品集團有限公司



HUBEI HAIXIN PROTECTIVE PRODUCTS GROUP CO., LTD



INDEX

- COMPANY
 - FACTORY
 - PRODUCTS
 - QUESTION/DISCUSSION
-

COMPANY INTRODUCTION

- ❑ Establish: Year 1994
- ❑ Specialize in: Disposable Medical Products and Personal Protective Products
- ❑ Type: Manufacturer



SPIRIT OF HUBEI HAIXIN GROUP



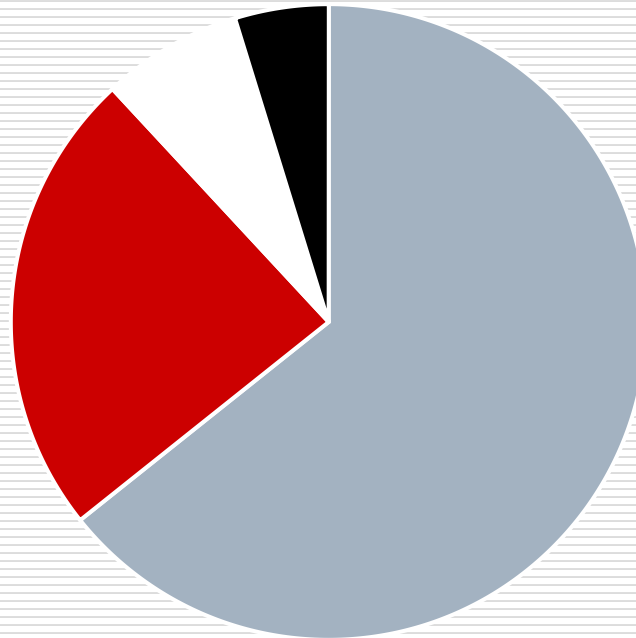
- PROVIDE OUR BEST QUALITY AND BEST PRICE WITH BEST SERVICE
-

MARKET





Sale Performance in 2017



■ USA 64%

■ ASIA 6%

■ EUROPE 25%

■ OTHERS 5%



MAIN CLIENTS



ULINE

ONEMED

pal[®]

MCKESSON



GranberG

AMG[®]



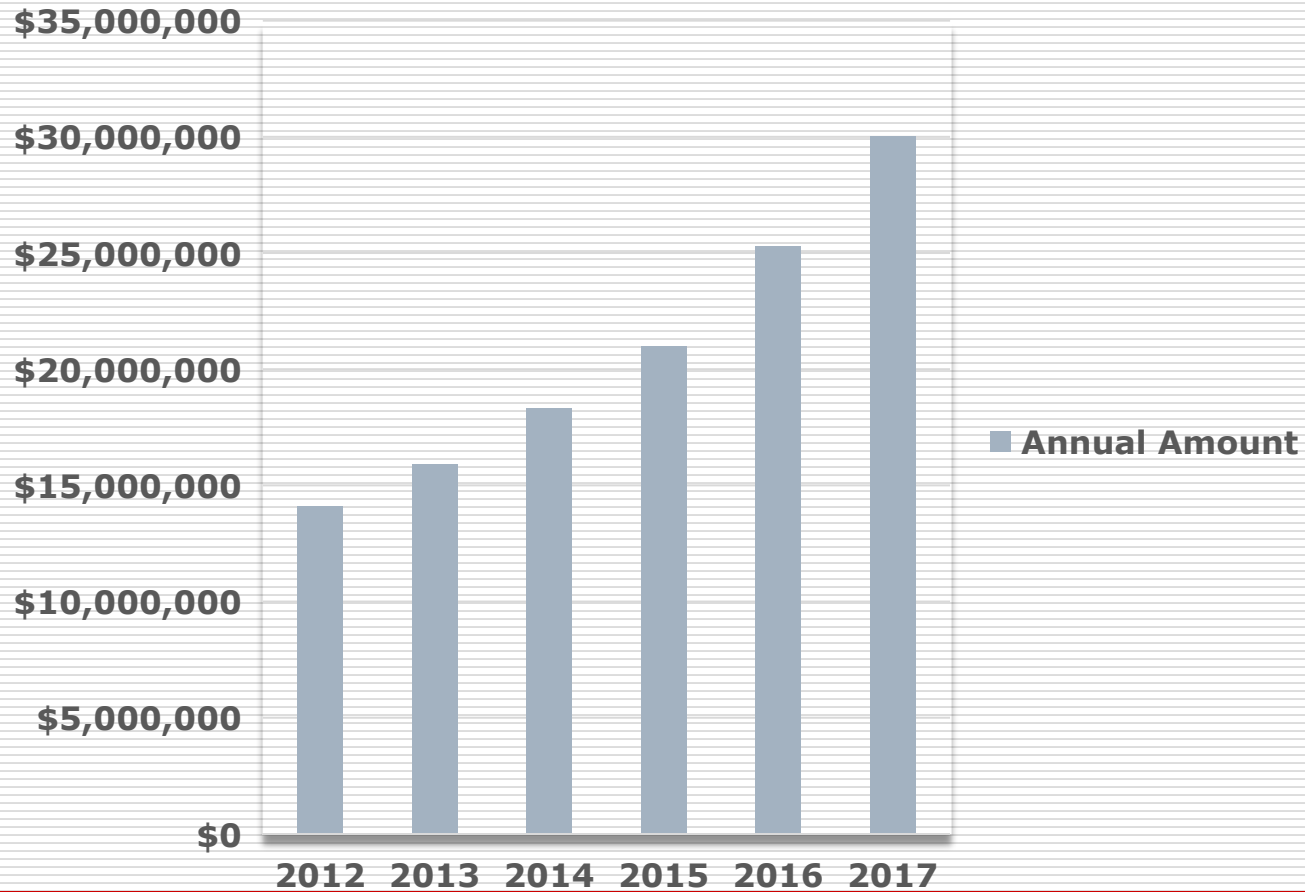
HENRY SCHEIN[®]

SINCERELY THANKS FOR COOPERATION



THE ANNUAL EXPORT

Annual Amount





HUBEI HAIXIN

CERTIFICATES

CERTIFICATE:


专业执照
(副本)

统一社会信用代码
91421087707022588A

扫描二维码
“国家企业信用信息公示系统”
了解更多信息
请登录、许可、监
督管理。

名称	湖北海兴卫生用品集团有限公司	注册资本	贰仟贰佰万圆整
类型	有限责任公司(自然人投资或控股)	成立日期	1999年05月20日
法定代表人	杨文春	营业期限	长期
经营范围	生产、实体店及网上销售：第一类医疗器械、第二类医疗器械、 次性无纺布制品、一次性塑料制品、一次性乳胶制品、2类或3类 进出口(国家禁止或涉及行政审批的货物和技术进出口除外)等 (涉及许可经营项目,应取得相关部门许可后方可经营)	所	湖北松滋经济开发区城东工业园金松大道 8-8号

登记机关
2020年03月20日



国家企业信用信息公示系统网址：<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

国家市场监督管理总局监制

CERTIFICATES



对外贸易经营者备案登记表

统一社会信用代码: 91421087707021588A
进出口企业代码: _____

经营者中文名称	湖北海兴卫生用品集团有限公司		
经营者英文名称	Hubei Haixin Protective Products Group Co., Ltd		
组织机构代码	_____	经营者类型	有限责任公司
住所	湖北松滋经济开发区城东工业园金桥大道8-8号		
经营场所(中文)	湖北松滋经济开发区城东工业园金桥大道8-8号		
经营场所(英文)	Hubei songzi economic development zone chen industrial park, jinqiao road 8-8		
联系电话	13807212130	联系手机	13982
邮政编码	434200	电子邮箱	hx-gong@163.com
工商登记注册日期	1999-3-10	注册号	_____

依法办理工商登记的企业填写以下内容


企业法定代表人姓名(中文)	有效证件号	420400196501121006
注册资本(人民币)	_____元	(折美元)

依法办理工商登记的企业或个体工商户(独资经营者)还应填写以下内容

企业法定代表人/个体工商户负责人姓名	有效证件号	_____
企业资产/个人财产	_____元	(折美元)

备注:
原产地证书备案号: 4201S#108

该表请认真阅读背面的条款, 并由企业法定代表人或个体工商户负责人签字、盖章。


 2016 年 08 月 12 日

CERTIFICATES



□ ISO 13485 CERTIFICATE

ZERTIFIKAT ♦ CERTIFICATE ♦ CERTIFICADO ♦ CERTIFICAT


Prod. of Service

CERTIFICATE
No. Q2N 07 01 51116 004

Holder of Certificate: Hubei Haixin Protective Products Co., Ltd.
No.206, Jiangnan Road
430070 Wuhan
PEOPLES REPUBLIC OF CHINA

Facility(ies): Hubei Haixin Protective Products Co., Ltd.
No.206, Jiangnan Road, 430070 Wuhan, PEOPLE'S REPUBLIC OF CHINA
Hubei Haixin Protective Products Co., Ltd.
No.168, Qube Street, Yuanshi, 434205 Sangzi / Wuhan,
PEOPLES REPUBLIC OF CHINA

Certification Mark: 

Scope of Certificate: Production and Distribution of Non-woven Products for Medical Use including Non-woven Caps, Non-woven Face Masks, Non-woven Gowns, Non-woven Shoe Covers, Plastic Products for Medical Use including PE or CPE Shoe Covers, Surgical Gowns

Applied Standard(s): ISO 13485:2003
Medical Devices - Quality Management Systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf!

Report No.: 7019862203
Valid until: 2009-05-31

Date: 2007-03-15 
Peter Krumm

Page 1 of 1

TÜV SÜD Product Service GmbH
Zertifizierstelle
Hilfenstr. 65 80339 München
Germany




Akkreditiert durch
Zentralrat der Länder
für Gesundheitsschutz
bei Arzneimittel-
 und Medizinprodukten
ZLG-ZQ-009.08.12-46



CE CERTIFICATE

□ Sterile Surgical Gown and Drapes

ZERTIFIKAT ♦ CERTIFICATE ♦ 注册证书 ♦ CERTIFICADO ♦ CERTIFICAT


Product Service

EC-CERTIFICATE
Production Quality Assurance System
(Annex V of the Directive 93/42/EEC on Medical Devices)
No. G2S 07 01 51116 005

Manufacturer: Hubei Haixin Protective Products Co., Ltd.
No.206, Jiangnan Road
430019 Wuhan,
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Giffenstrasse 40
20037 Hamburg
GERMANY

Product Category(ies): Surgical Gowns

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture according to Annex V, section 2 of the Directive 93/42/EEC on Medical Devices. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective product / product categories and conforms to the provisions of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 70199925203
Valid until: 2008-01-06

Date: 2007-02-16

Rainer Krumme




TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

Page 1 of 2

TÜV SÜD Product Service GmbH · Zertifizierungsbüro · Rillerstrasse 65 · 80329 München · Germany

ZERTIFIKAT ♦ CERTIFICATE ♦ 注册证书 ♦ CERTIFICADO ♦ CERTIFICAT


Product Service

EC-Certificate
Production Quality Assurance System
(Annex V of the Directive 93/42/EEC on Medical Devices)
No. G2S 07 01 51116 005

Facility(ies): Hubei Haixin Protective Products Co., Ltd.
No.206, Jiangnan Road, 430010 Wuhan, PEOPLE'S REPUBLIC OF CHINA

Hubei Haixin Protective Products Co., Ltd.
No.168, Gule Street, Yuanshi, 434205 Songzi / Wuhan, PEOPLE'S REPUBLIC OF CHINA

Page 2 of 2


TÜV SÜD Product Service GmbH · Zertifizierungsbüro · Rillerstrasse 65 · 80329 München · Germany



FDA Registration (510K)

510K NO: K123787 (FOR SURICAL FACE MASK)

510K NO: K171535 (FOR SURGICAL ISOLATION GOWN)



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[1 result found for Establishment Registration Number : 3004158259](#)
[New Search](#)

Establishment Name	Registration Number	Current Registration Yr
Hubei Haixin Protective Products Group Co., Ltd CHINA	3004158259	2016
<ul style="list-style-type: none"> • Shoe And Shoe Cover, Conductive - NONWOVEN NON-SKID SHOECOVER, Nonwoven Shoe Cover 		Manufacturer
<ul style="list-style-type: none"> • Non-Surgical Isolation Gown - Non-Surgical Isolation Gown 		Manufacturer
<ul style="list-style-type: none"> • Cover, Shoe, Operating-Room 		Manufacturer
<ul style="list-style-type: none"> • Cap, Surgical - Bouffant Cap 		Foreign Exporter; Manufacturer
<ul style="list-style-type: none"> • Accessory, Surgical Apparel - Lab Coat/Lab Jacket 		Manufacturer
<ul style="list-style-type: none"> • Gown, Surgical - Surgical Gown 		Manufacturer
<ul style="list-style-type: none"> • Gown, Surgical 		Contract Manufacturer; Foreign Exporter
<ul style="list-style-type: none"> • Drape, Surgical 		Contract Manufacturer; Foreign Exporter
<ul style="list-style-type: none"> • Mask, Surgical - Surgical Mask, Procedure Mask 		Foreign Exporter; Manufacturer
<ul style="list-style-type: none"> • Bedding, Disposable, Medical - Bedding, Cot Sheets, Disposable Red Sheet, Equipment Cover, Lifeneed Bed Sheet, Medical Sheets, Nonwoven Bed Sheets 		Foreign Exporter; Manufacturer
<ul style="list-style-type: none"> • Gown, Examination 		Manufacturer
<ul style="list-style-type: none"> • Suit, Surgical 		Manufacturer

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FDA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE



Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

Hubei Haixin Protective Products Group Co.,Ltd
Jinsong Avenue 8-8,Chengdong Industrial Zone, Songzi City, Hubei,
434205, CHINA

has completed the FDA Establishment Registration (as manufacturer / contract manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA Communications: **SUNGO TECHNICAL SERVICE INC.**
6050 W EAST WOOD AVE CHICAGO,
ILLINOIS 60630, USA
Telephone: +1-855-957-5555 Email: sungo.group@yahoo.com

Registration Number: 300 [REDACTED]
Device Listing#: See annex [REDACTED]

SUNGO Technical Service Inc. will maintain this registration remains effective upon request and presentation of this certificate until the calendar year stated above, unless said registration is terminated after issuance of a certificate. SUNGO Technical Service Inc. makes no other representations or warranties. This certificate make any representations or warranties to any person or entity other than the certificate holder, for whose sole benefit it is issued. This certificate does not denote approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in the foregoing.

Pursuant to 21 CFR 312.19, "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. SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.



Sungo FDA
global service



Executive Director
Issued: Mar. 19 2020
Cert. No.: 2007US053515
Expiration Date: Dec. 31 2020
CERTIFIED

Type 5&6 For Coverall

CENTROCOT



EU TYPE-EXAMINATION CERTIFICATE

No CE 1078180740 -00 -00

According to "Regulation (EU) 2010/425 of the European Parliament and of the Council" of 9th March 2010 on Personal Protective Equipment and repealing Council Directive 89/686/EEC

Centro Tessile Cottoniero e Abbigliamento S.p.A.
P.zza Sant'Anna, 2 - 21052 Busto Arsizio (VA) - Italia

EEC Notified Body N° 0524

- in view of the firm's application submitted on: 24.10.2018;
- in view of the positive results of the Technical File verification submitted by the manufacturer together with the above mentioned request;
- in view of the manufacturer's declaration stated in the Technical File attached to the above mentioned request
- having verified that technical specification of design and manufacture is in compliance with basic requirements specified in annex II of Regulation (EU) 2010/425 and that technical manufacturing documentation is in compliance with above mentioned specifications;
- in view of the positive test results carried out on the basic model representative of production according to paragraph 4 of annex V of Regulation (EU) 2010/425 and to Standards:

EN 13034:2005+A1:2009, EN ISO 13962-1:2004+A1:2010,
EN 1145-5:2008

Issues to:

Hubei Haixin Protective Products Group Co. Ltd
Jinshong Avenue, No.8-8, Chengdong Industrial Zone, Songzi

the EU Type-Examination Certificate concerning the following PPE model:

Chemical protective coverall
GREEN CROSS 2000 PROTECTIVE COVERALL

Category III (fluid)

The mode of Personal Protective Equipment is subject to conformity to type assessment according to Section 19 of Regulation (EU) 2010/425 (Module G2 or D)



PROT. N° 2020 - 040 N° 0020
L. 07.07.2018
Ministero di Int. Affari, Roma, Italia

Page 1 / 2

CENTROCOT



Basic type description

GREEN CROSS 2000
PROTECTIVE
COVERALL

Thin-linear material, with hood, zipper at front opening covered by flap elastic cuffs, ankles and foot, cut and sewn seams, white colour, fabric: 540 100% polypropylene 30 g/m²



Variants description

No variants

Sizes

From S to XXL

Standards

EN ISO 13034:2005	Protective clothing - general requirements
EN ISO 13962-1:2004 +A1:2010	Protective clothing for use against solid particulates - Part 1: Performance requirements for chemical protective clothing providing protection to the full body against either solid particulates
EN 13034:2005+A1:2009	Protective clothing against liquid chemicals - Performance requirements for chemical protection clothing offering limited protective performance against liquid chemicals
EN 1145-5:2008	Protective clothing - Electrostatic properties - Part 5: Material performance and design requirements
EN 14325:2004	Protective clothing against chemicals - Test methods and performance classification of chemical protective clothing materials: seams, joints and assemblages

EU type-examination certificate No. CE 1078180740-00-00 Hubei 18101

Page 2 / 2



PROT. N° 2020 - 040 N° 0020
L. 07.07.2018
Ministero di Int. Affari, Roma, Italia

CENTROCOT



Performance levels

EN ISO 13962-1	Type 5	protection against airborne solid particulates and infective agents
EN 13034	Type 6	limited protective performance against light spray, liquid aerosol or low pressure, low volume splashes and infective agents

Use

Clothing to be worn to protect against light spray, airborne solid particulates with aerosols bioagents
Other uses than those listed above are excluded.

Tests

The test results are included in the report: 18NA11352, 18PA11353, 18RA11358

Marking

The following information are listed on the label inside the garment

- ED marking
- Company name
- Article code
- Standards
- Standardized pictograms
- Maintenance symbols
- PPE category

Validity

- This certificate has 5-year validity from issue date. On expiration date the Manufacturer will be responsible to require the renewal.
- The applied standards are still in force currently valid at issue date of this Certificate. The certificate validity is not concerned in case of reviewed standards before the expiry date.
- Any change of model and materials object of this Certificate shall be notified and then approved by Centrocot.

The certificate must be held by the manufacturer and must be shown, requested both by the authorities entities or by notified bodies

Busto Arsizio,

issue date:
24th October 2018
Expiry date:
24th October 2023



General Manager
Dr. Grazia Conni
Grazia Conni

EU type-examination certificate No. CE 1078180740-00-00 Hubei 18101

Page 3 / 3



PROT. N° 2020 - 040 N° 0020
L. 07.07.2018
Ministero di Int. Affari, Roma, Italia

HEAD OFFICE (WUHAN)



BRANCH

海興綠十字醫療器材有限公司



Haixin Green Cross Medical Products Co.,Ltd.

FACTORY I





FACTORY (I)INTRODUCTION

- ❑ Factory I: 168 Gule Street, Yuanshi, Songzi City, Hubei
 - ❑ Establish: Year 1998
 - ❑ Production area: 20,268 m²
 - ❑ Employee: 800 staffs
 - ❑ Workshop: Apparel (Iso Gown,CPE Gown,Lab coat,Coverall)
Face mask (300,000 grade cleanroom)
Accessory (Caps,Shoecovers)
-

FACTORY II





FACTORY (II) INTRODUCTION

- ❑ Factory II: Yongxin Avenue No.2, Songzi City, Hubei Province
 - ❑ Establish: Year 2014
 - ❑ Production area: 20443m²
 - ❑ Employee: 350 staffs
 - ❑ Workshop: Sterile Surgical Gowns (100,000 grade cleanroom)
 - ❑ Sterile Surgical Drapes (100,000 grade cleanroom)
-

APPAREL WORKSHOP



CPE GOWN WORKSHOP





SURIGICAL MASK WORKSHOP



SURGICAL GOWN & DRAPES



AAMI PB70 LEVELS

ANSI/AAMI PB70 Barrier Performance	Test Method	Test Definition	Requirement
Level 1	Water Resistance: Impact Penetration AATCC 42	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact	Water Impact \leq 4.5g
Level 2	Water Resistance: Impact Penetration AATCC 42 Water Resistance: Hydrostatic Pressure AATCC 127	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact AATCC 127 Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.	Water Impact \leq 1.0g Hydrostatic Pressure \geq 20cm
Level 3	Water Resistance: Impact Penetration AATCC 42 Water Resistance: Hydrostatic Pressure AATCC 127	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact AATCC 127 Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.	Water Impact \leq 1.0g Hydrostatic Pressure \geq 50cm
Level 4	Viral Penetration ASTM F1671	ASTM 1671 Measures the resistance of fabrics to blood borne pathogens using viral penetration at 2psi and ambient pressure.	Total Impervious



QUALITY STANDARDS

**ISO
13485**

Medical devices-Quality management systems-
Requirements for regulatory purposes

**ISO
9001**

The quality management systems of Hubei Haixin is in
conformity of ISO 9001 standard

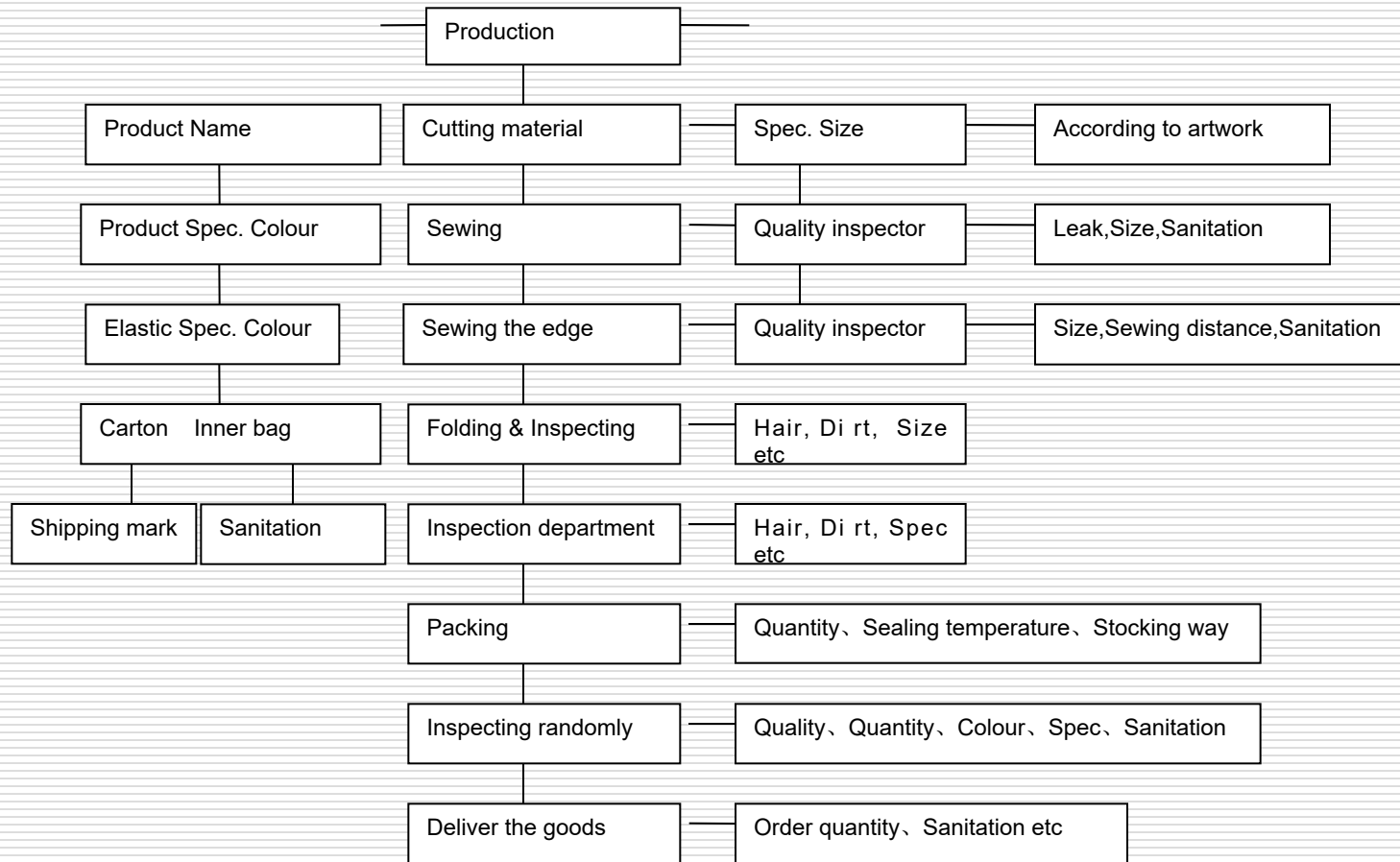
CE

A quality assurance system for manufacturer in
accordance with Medical Devices Annex V.(Devices in
class 1 in sterile conditions,sterilised systems or
procedure packs)

**EN
13034**

This EC type-examination certificate refers to Haixin's
SMS coverall complies with the essential requirements
of Annex II of the directive and reach Type 6 standard.

PROCESS FLOW



PROCESS FLOW



PROCESS FLOW



AIRSHOWER ROOM



PRODUCTION ROOM



LAB



PACKING ROOM



WAREHOUSE





HUBEI HAIXIN

HEADWEAR PROTECTION





HUBEI HAIXIN

NONWOVEN FACE MASK





HUBEI HAXIN

BODYWEAR PROTECTION





HUBEI HAIXIN

FOOTWEAR PROTECTION





SURGICAL GOWN





HUBEI HAIXIN

SURGICAL DRAPE

www.hh-haixin.com

Laparotomy Drape

Code No.	GCB-019
Size	325*266cm
Rminforcement	40*75cm
Feature	Ladder-shaped fenestration

Extremity Drape

Code No.	GCB-020
Size	310*335cm
Rminforcement	760*165cm
Feature	8.5cm expandable fenestration, ribe holders

Extremity Drape

Code No.	GCB-021
Size	210*324cm
Fenestration	180*180cm
Feature	6.5cm expandable fenestration, ribe holders

Hip Drape

Code No.	GCB-022
Size	310*320cm
Fenestration	52*160cm
Feature	expandable fenestration, fluid pouch and support wire, ribe holders

Hip Drape

Code No.	GCB-023
Size	292*325cm
Reinforcement	52*140cm
Feature	expandable fenestration, fluid pouch and support wire

Arthroscopy Drape

Code No.	GCB-024
Size	300*300cm
Rminforcement	90*180cm
Feature	19*15cm oval expandable fenestration, fluid pouch

Arthroscopy Drape

Code No.	GCB-025
Size	447*306cm
Reinforcement	40*55cm
Feature	11*15cm expandable fenestration, fluid pouch and support wire, side view pouch

Tur Drape

Code No.	GCB-026
Size	250*165cm
Rminforcement	165cm
Feature	finger cut, pouch with mesh and drain port

www.hh-haixin.com

Tur Drape

Code No.	GCB-027
Size	266*186cm
Fenestration	6cm
Feature	Drain port, pouch with mesh and drain port

Brachial Drape

Code No.	GCB-028
Size	75*100cm
Feature	1.5*1.5cm oval fenestration with adhesive, 1/2" tape to corner

Brachial Drape

Code No.	GCB-029
Size	100*75cm
Feature	7.5*9cm oval fenestration, 1/2" tape

Split U Drape

Code No.	GCB-030
Size	150*200cm
Feature	arch15*9.3cm, 1/2" tape

Craniotomy Drape

Code No.	GCB-031
Size	245*256cm
Rminforcement	43*76cm
Feature	18*20cm oval fenestration with foam, fluid pouch

Caesarean Drape

Code No.	GCB-032
Size	240*312cm
Reinforcement	45*55cm
Feature	fenestration with foam, fluid pouch with support wire, side view pouch

Caesarean Drape

Code No.	GCB-033
Size	343*310cm
Feature	fluid pouch, with support wire and drain port, foam, 50*55cm, ribe holders

Angiography Drape

Code No.	GCB-034
Size	210*370cm
Reinforcement	82.5*37.0cm
Feature	fenestration, square fenestration, 1/2" tape with foam, side view pouch



MISSION&PROSPECT

□ MISSION

-----Caring the clients'needs as our own needs, making our name known to the world

□ PROSPECT

-----With the excellent quality and competitive price, we're confident that our products will lead us a brighter future.

THE END



Looking forward to cooperating
with you!

