



编号 320281666202003100217

统一社会信用代码

91320281695497366N (1/1)

营业执照

(副本)



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名称

[Redacted Name]

注册资本 409.675201万元整

类型

有限责任公司(法人独资)

成立日期 2009年10月23日

法定代表人

陈顺勇

营业期限 2009年10月23日至2040年10月22日

经营范围

手术衣、洞巾、其他一类医疗器械的制造、加工、销售；自营和代理各类商品及技术的进出口业务，但国家限定企业经营或禁止进出口的商品和技术除外。医用口罩生产；日用口罩（非医用）生产；医护人员防护用品生产（Ⅱ类医疗器械）；特种劳动防护用品生产；（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）

住所

[Redacted Address]

登记机关



2020年03月10日



邓白氏注册™
D-U-N-S® REGISTERED™

邓白氏注册™ 认证企业

(2019年7月至2021年7月)

邓白氏编码®: 421255805



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医疗物资英文

xlsx	A	B	C	
66		苏州鼎康进出口有限公司 Suzhou Acmed Import & Export Co., Ltd.	91320505792300764J	U.S. FDA
67		佛山市南海康得福医疗用品有限公司 Foshan Nanhai Plus Medical Co Ltd	91440605782976648A	U.S. FDA
68		常州好利医疗器械有限公司 Changzhou Holymed Products Co., Ltd	913204127812539312	U.S. FDA
69		宏昌生物医疗科技（平湖）有限公司 Principle & Will Biotech (Pinghu) Co., Ltd.	913304007511953988	U.S. FDA
70		施洁医疗技术（上海）有限公司 Sterigenics Shanghai Eto Ltd.	91310000785178414H	U.S. FDA
71		合肥汉邦希瑞护理用品有限公司 S.E.S. Healthcare Products Co., Ltd.	91340121680809902E	U.S. FDA
72		江苏稳德福无纺科技有限公司 Jiangsu Wonderful Nonwoven Technology Co., Ltd.	913213003105795568	U.S. FDA
73		江西美宝利医用敷料有限公司 Medwell Medical Products Co., Ltd.	91360426716524387R	U.S. FDA
74		宏昌生物医疗科技（仙桃）有限公司 Principle & Will Biotech (Xiantao) Co. Ltd	914290046797819142	U.S. FDA
75		[REDACTED]	91320281695497366N	U.S. FDA
76		威海鸿宇无纺布制品有限公司 Weihai Hongyu Nonwoven Fabric Products Co., Ltd	91371000699692898J	U.S. FDA
77		盐城艾达无纺布制品有限公司 Yancheng Aieda Non Woven Products Co Ltd	913209005558019958	U.S. FDA
78		上海市医药保健品进出口有限公司 Shanghai Medicines & Health Products Imp. & Exp. Co., Ltd.	913101011322082259	U.S. FDA
79		史帝瑞灭菌技术（苏州）有限公司 Steris Sterilization Technologies (Suzhou) Ltd	9132059467010735XN	U.S. FDA
80		连云港艾信无纺布制品有限公司 Lianyungang Anson Non-Woven Product Co., Ltd.	91320700561824309D	U.S. FDA

Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

DAkks

Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q6 072348 0013 Rev. 00

Holder of Certificate:



Certification Mark:



Scope of Certificate:

Production and Distribution of
Sterile Equipment Cover, Surgical Gown,
Surgical Drape, Scope Warmer,
Surgical Pack

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.:

SH1858911

Valid from:

2019-01-22

Valid until:

2021-12-31

Date,

2019-01-22

Stefan Preiß

Certificate

No. Q6 072348 0013 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

[Redacted facility information]



→ SURGICAL GOWNS

→ ISOLATION GOWNS

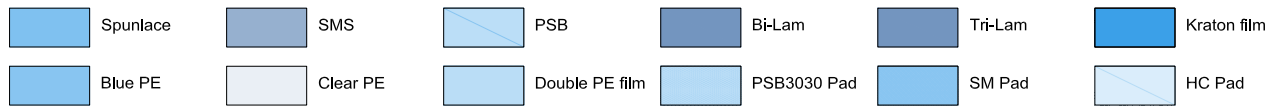
江阴飘迈医疗用品有限公司

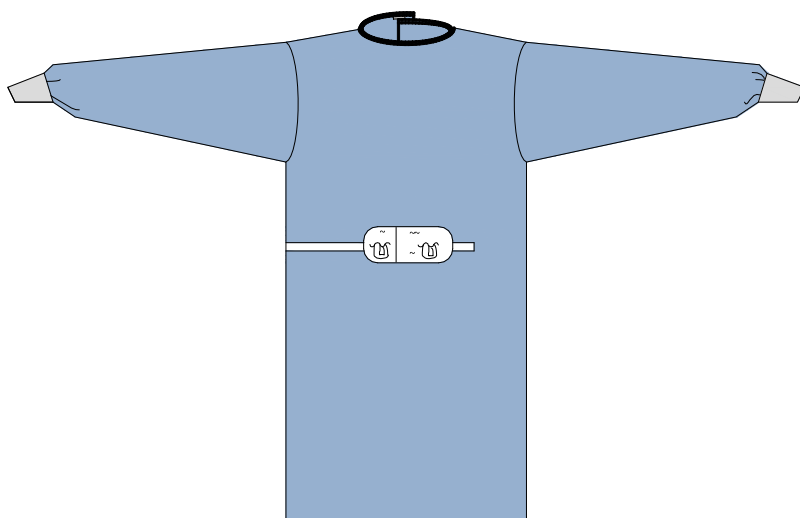
Jiangyin PureMED Products Co.,LTD.

SURGICAL GOWN		
Number	Description	Page
PM5001	SMS StandardM115X130cm	1
PM5101	SMS StandardL122X153cm	1
PM5201	SMS Standard XL127X172cm	1
PM5301	SMS Standard XXL134X190cm	1
PM5501	SMS Standard XL-XLONG 145X172cm	1
PM5601	SMS Standard XXL-XLONG 145X190cm	1
PM5003	Spunlace StandardM115X130cm	2
PM5103	Spunlace StandardL122X153cm	2
PM5203	Spunlace Standard XL127X172cm	2
PM5303	Spunlace Standard XXL134X190cm	2
PM5503	Spunlace Standard XL-XLONG 145X172cm	2
PM5603	Spunlace Standard XXL-XLONG 145X190cm	2
PM5004	Poly ReinforcedM115X130cm	3
PM5104	Poly ReinforcedL122X153cm	3
PM5204	Poly Reinforced XL127X172cm	3
PM5304	Poly Reinforced XXL134X190cm	3
PM5504	Poly ReinforcedXL-XLONG 145X172cm	3
PM5604	Poly ReinforcedXXL-XLONG 145X190cm	3
PM5006	Fabric ReinforcedM115X130cm	4
PM5106	Fabric ReinforcedL122X153cm	4
PM5206	Fabric Reinforced XL127X172cm	4
PM5306	Fabric Reinforced XXL134X190cm	4
PM5506	Fabric ReinforcedXL-XLONG 145X172cm	4
PM5606	Fabric ReinforcedXXL-XLONG 145X190cm	4

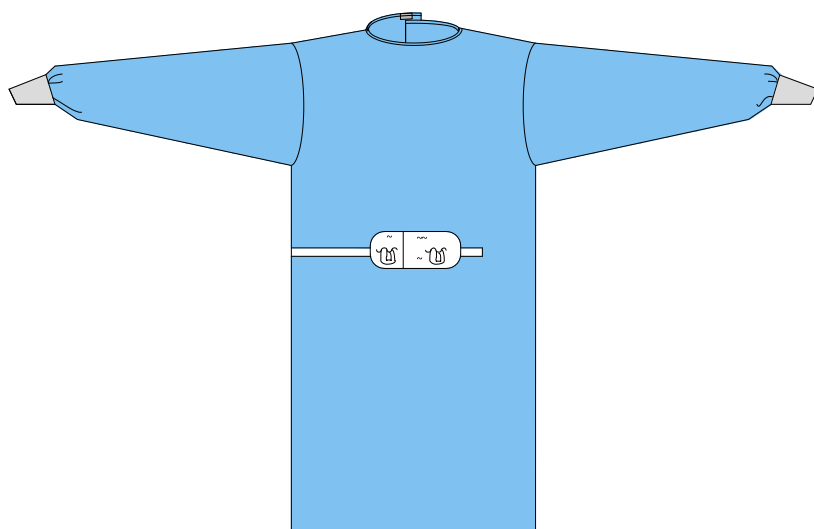
ISOLATION GOWN		
Number	Description	Page
PI001	L 115x136cm	5
PI002	XL120X142cm	5

Material Color:

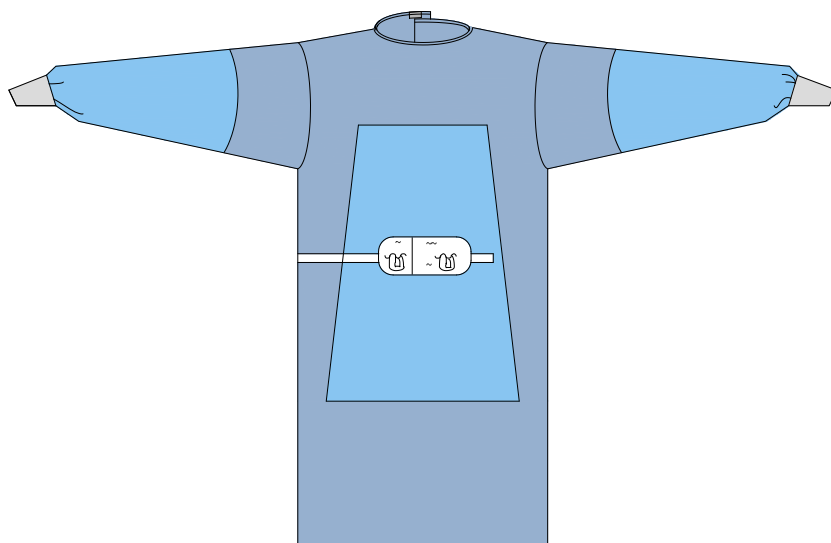




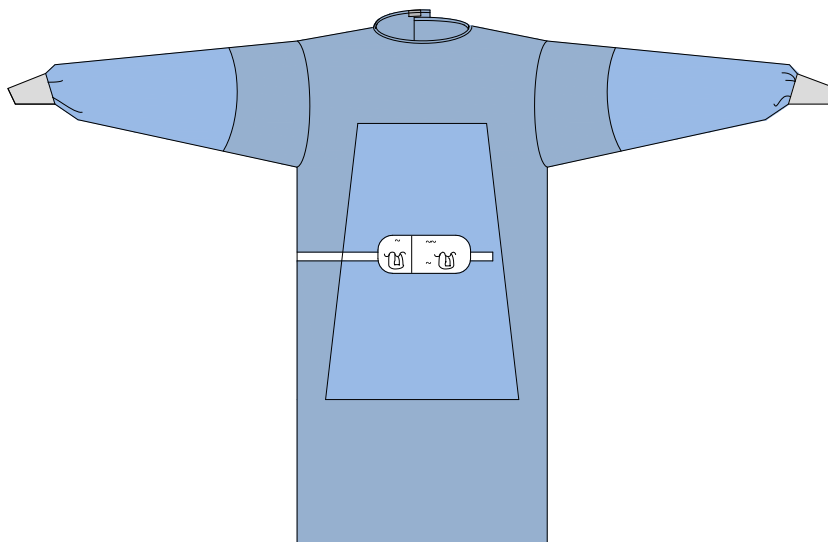
Code	Size	Type	Dimension of Body Panel
PM5001	M	SMS Standard	115X130cm
PM5101	L	SMS Standard	122X153cm
PM5201	XL	SMS Standard	127X172cm
PM5301	XXL	SMS Standard	134X190cm
PM5501	XL-XLONG	SMS Standard	145X172cm
PM5601	XXL-XLONG	SMS Standard	145X190cm
Standard gown is for relatively dry procedures			
All gowns with knitted cuff and Velcro hook & pile			
All gowns are latexfree			
All gowns comply with EN 13795 & AAMI 3			



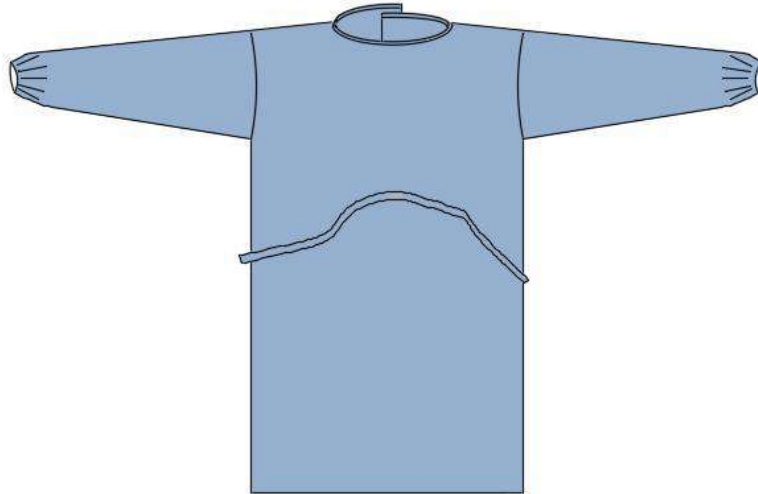
Code	Size	Type	Dimension of Body Panel
PM5003	M	Spunlace Standard	115X130cm
PM5103	L	Spunlace Standard	122X153cm
PM5203	XL	Spunlace Standard	127X172cm
PM5303	XXL	Spunlace Standard	134X190cm
PM5503	XL-XLONG	Spunlace Standard	145X172cm
PM5603	XXL-XLONG	Spunlace Standard	145X190cm
Standard gown is for relatively dry procedures			
All gowns with knitted cuff and Velcro hook & pile			
All gowns are latexfree			
All gowns comply with EN 13795			



Code	Size	Type	Dimension of Body Panel	Dimension of Chest Reinforcement
PM5004	M	Poly Reinforced	115X130cm	40/59X85cm
PM5104	L	Poly Reinforced	122X153cm	40/59X85cm
PM5204	XL	Poly Reinforced	127X172cm	51/70X85cm
PM5304	XXL	Poly Reinforced	134X190cm	51/70X85cm
PM5504	XL-XLONG	Poly Reinforced	145X172cm	51/70X85cm
PM5604	XXL-XLONG	Poly Reinforced	145X190cm	51/70X85cm
Poly reinforced SMS gown is for high level wet procedures				
All gowns with knitted cuff and Velcro hook & pile				
All gowns are latexfree				
All gowns comply with EN 13795& AAMI 3				



Code	Size	Type	Dimension of Body Panel	Dimension of Chest Reinforcement
PM5006	M	Fabric Reinforced	115X130cm	40/59X85cm
PM5106	L	Fabric Reinforced	122X153cm	40/59X85cm
PM5206	XL	Fabric Reinforced	127X172cm	51/70X85cm
PM5306	XXL	Fabric Reinforced	134X190cm	51/70X85cm
PM5506	XL-XLONG	Fabric Reinforced	145X172cm	51/70X85cm
PM5606	XXL-XLONG	Fabric Reinforced	145X190cm	51/70X85cm
Poly reinforced gown is for midium level wet procedures				
All gowns with knitted cuff and Velcro hook & pile				
All gowns are latexfree				
All gowns comply with EN 13795& AAMI 3				



Code	Size	Dimension of Body Panel
PI001	L	115X136cm
PI002	XL	120X142cm
Type:PSB、SMS、PSB/PE、Spunlace/PE		
Standard gown is for relatively dry procedures		
All gowns are latexfree		