ZHONGTAI

营业执照 （Business Licence）

统一社会信用代码
91429004753430005D

营业执照

（副 本）

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 仙桃市中泰防护用品股份有限公司

类 型 其他股份有限公司(非上市)

法定代表人 许龙

经营范围 第一类医疗器械，第二类医疗器械（6864医用卫生材料及敷料）生产及销售；无纺布制品、塑料制品、纸制品、无纺布机械的生产、加工及销售；自营和代理各类商品及技术进出口业务（国家限定或禁止进出口的商品及技术除外）。（涉及许可经营项目，应取得相关部门许可后方可经营）

注册资本 叁佰万圆整

成立日期 2003年10月10日

营业期限 长期

住 所 仙桃市彭场镇太子湖工业园

登记机关 仙桃市市场监督管理局

2019 年 7 月 24 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

医疗器械生产许可证 （Medical device production Licence）

医疗器械生产许可证

许可证编号：鄂食药监械生产许 20160724

企业名称：仙桃市中泰防护用品股份有限公司

生产地址：湖北省仙桃市彭场镇太子湖工业园

法定代表人：许龙

生产范围：
二类：6864 医用卫生材料及敷料。***

企业负责人：许龙

住 所：湖北省仙桃市彭场镇太子湖工业园

发证部门：湖北省食品药品监督管理局

有效期限：至 2021 年 10 月 30 日

发证日期：2017 年 06 月 26 日

国家食品药品监督管理总局制

ZHONGTAI

生产车间图 （Production Line）

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手术衣注册证 (Registration Certificate of Surgical Gown)

中华人民共和国医疗器械注册证

注册证编号：鄂械注准 20162642410

注册人名称	仙桃市中泰防护用品有限公司
注册人住所	仙桃市彭场镇太子湖工业园
生产地址	仙桃市彭场镇太子湖工业园
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	100cm×130cm（S）、110cm×135cm（M）、115cm×137cm（L）、120cm×140cm（XL）、125cm×145cm（XXL）。卫生级别为灭菌级。
结构及组成	本品选用 SMS 三层复合无纺布为主体材料，关键区域加贴一层 PE 淋膜复合无纺布，一次性使用手术衣由前身、后身、袖子、系带等组成。
适用范围	用于防止手术过程和其他有创检查中病人和医护人员之间感染原的传播。其中高性能手术衣适用于病人血液中已知有传染性病毒或紧急抢救时未知血液中是否有传染性病毒的手术。
附件	产品技术要求
其他内容	
备注	

审批部门：湖北省食品药品监督管理局　　批准日期：2016 年 09 月 09 日

有效期至：2021 年 09 月 08 日

（审批部门盖章）

ZHONGTAI

CE 认证（EC Certificate）

TÜVRheinland

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60139107 0001

Report No.: 15065841 009

Manufacturer: Xiantao Zhongtai Protective Products Co., Ltd.
3#, Taizi Lake Industry Park
Pengchang Town, Xiantao City
433018 Hubei Province
P.R. China

Products: Aspects of manufacture concerned with securing and maintaining sterile conditions of Face Masks, Surgical Gowns, Surgical Caps, Surgical Drapes, Surgical Drape Packs

Replaces Approval, Registration No.: DD 60091096 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-01-23

Date: 2020-01-23

Notified Body
Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

ZHONGTAI

EN13795 证书及检测报告 （EN 13795 Certificate & Test Report）

ISTITUTO SERVIZI EUROPEI TECNOLOGICI

ISET S.r.l. Unipersonale

Sede Legale e Uffici — Via Donatori di sangue, 9 - 46024 Moglia (MN) — Tel. e fax +39 (0)376 598063 — www.iset-italia.eu iset@iset-italia.com

Cap. soc. i.v. € 10.200,00 — Cod. Fisc. e P.IVA Reg. Imprese 02332 750369 — REA 02332 750369 — Cap. soc. i.v. MN 0221098

CERTIFICATE

Certificat - Certificado- Сертификат - Zertifikat - 證書

1) **APPLICANT:** (who finally puts the product on the market)
XIANTAO ZHONGTAI PROTECTIVE PRODUCTS CO.,LTD.
#3,Taizi Lake Industry Park, Pengchang Town, Xiantao City, Hubei Province, China
2) **CERTIFICATE NO.:** IMSETC.000720191114
FILE REFERENCE: TCF-102401-MDD
3) **ISET MARK:**

4) **CAUTION ABOUT CE MARKING** (Instruction for the Applicant who puts the product on the EU market):
The label of the CE Marking on the left side should be not less than 5mm height. CE Marking and EC Declaration of Conformity are duties for the manufacturer or its applicant who puts the product on the market. This one is responsible to start the CE marking and certification procedure as required by the legislation in force. Only for the products which are compulsorily included into specific Directives or Regulations will be necessary to appoint a Notified Body.
5) **TYPE OF PRODUCT:** Surgical Gown
TRADE MARK:
MODEL(S): ZT-11-2, ZT-11-1
6) **LIST OF DIRECTIVES / REGULATIONS /STANDARDS** (as declared by the manufacturer itself)
Medical Device Directive 93/42/EEC
EN 13795:2011+A1:2013
7) **NOTE:** The applicant is aware about the contents and information included in the ModCOM04.06 Regulation for this type of Certificate that is considered totally accepted. The latest revision of the Regulation is available and can be downloaded from the website www.iset-italia.eu. This document is not referred to any evaluation that could be considered as included in the scope of the activities covered by the standard BS EN ISO/IEC 17065:2012 or European Regulation 765/2008.
8) **REMARK:** Certificate is issued on voluntary application from the Client and it gives to the applicant the right to use and affix the ISET Mark (at point 3) on their products, even if it doesn't imply any assessment on the safety and compliance of the product. ISET declares that the only scope of the assessment is to verify the existence of the declaration issued by the manufacturer or an applicant under its own responsibilities.
9) **DATE OF ISSUE:** 14/11/2019 **EXPIRY DATE:** 13/11/2024
10) **SIGNATURE:** Li Zhang
(On behalf of the Legal representative)

ISTITUTO SERVIZI EUROPEI TECNOLOGICI — ISET S.R.L

ZHONGTAI

Applicant	XIANTAO ZHONGTAI PROTECTIVE PRODUCTS CO.,LTD. #3,Taizi Lake Industry Park, Pengchang Town, Xiantao City, Hubei Province, China
Manufacturer	The same as applicant

Test Item	Surgical Gown
Mark of origin	N/A
Type Designation(s)	ZT-11-2,ZT-11-1
Serial No(s)	Prototype

Test requirements	**EN 13795:2011+A1:2013**
Test result	The test item passed the test requirement(s).

Testing Laboratory	Shanghai MICEZ Equipment Testing & Technical Co., LTD
Testing location	At manufacturer's premises

Compiled by (+ signature)	Eric. Zhang **Eric. Zhang** Shanghai MICEZ Equipment Testing & Technical Co., LTD
Approved by (+ signature)	Thomas **Thomas** Shanghai MICEZ Equipment Testing & Technical Co., LTD
Date of issue	2019-Nov.-18

Other Aspects:

This report is only valid together with 1 parts which named -01

General remarks:

The test result presented in this report relate only to the object(s) tested.

This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

"(see Annex #)" refers to additional information appended to the report.

"(see appended table)" refers to a table appended to the report.

Throughout this report a point is used as the decimal separator.

Additional Information :

Abbreviations used in this report :

None

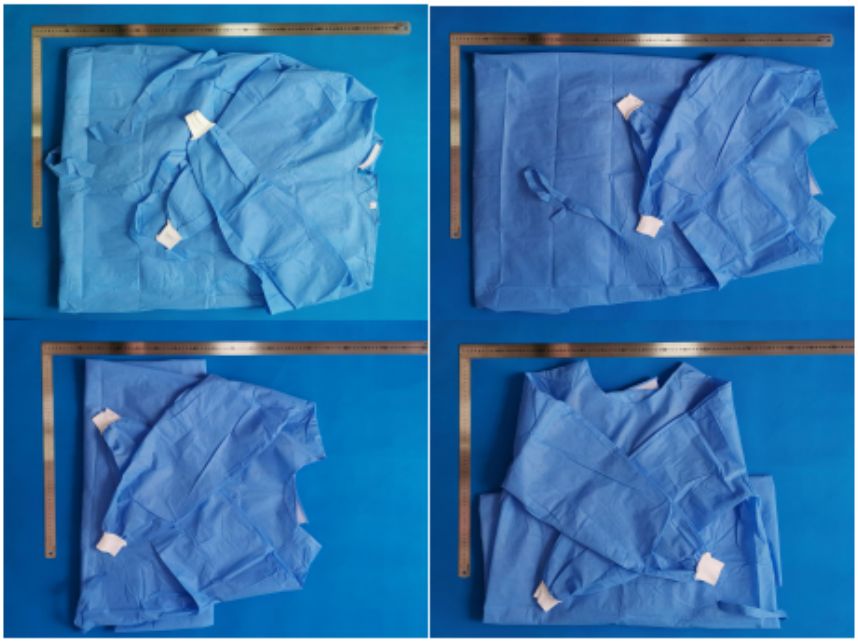
Others:

None

Brief description of the test item:

/

Pictures of product:



EN 13795:2011+A1:2013

Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels

Clause	Requirements - Test	Result - Remark	Verdict
1	**Scope**		-
2	**Normative references**		-
3	**Terms and definitions**		-
4	**Performance requirements**		P
	To comply with EN 13795, products shall meet all the requirements specified in either Tables 1, 2 or 3 (as appropriate to the product), when tested according to this European Standard throughout their useful life. If the intended purpose of a medical device specifies the use as a sterile field the requirements for surgical drapes and equipment covers apply as perTable2		P

Table 1 — Characteristics to be evaluated and performance requirements for surgical gowns

Characteristic	Test method (for references, see Clause 2)	Unit	Requirement			
			Standard performance		High performance	
			Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration — Dry	EN ISO 22612	CFU	Not required	≤ 300 [a]	Not required	≤ 300 [a]
Resistance to microbial penetration — Wet	EN ISO 22610	t_B	≥ 2,8 [b]	Not required	6,8 [b,c]	Not required
Cleanliness — Microbial	EN ISO 11737-1	CFU/ 100 cm²	≤ 300	≤ 300	≤ 300	≤ 300
Cleanliness — Particulate matter	EN ISO 9073-10	IPM	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5
Linting	EN ISO 9073-10	$\log_{10}$ (lint count)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0
Resistance to liquid penetration	EN 20811	cm H_2O	≥ 20	≥ 10	≥ 100	≥ 10
Bursting strength — Dry	EN ISO 13938-1	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength — Wet	EN ISO 13938-1	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength — Dry	EN 29073-3	N	≥ 20	≥ 20	≥ 20	≥ 20
Tensile strength — Wet	EN 29073-3	N	≥ 20	Not required	≥ 20	Not required

[a] Test conditions: challenge concentration 10^6 CFU/g talc, and 30 min vibration time.

[b] The Least Significant Difference (LSD) for t_B when estimated using EN ISO 22610, was found to be 0,98 at the 95 % confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. Thus materials varying by up to 0,98 t_B are probably not different; materials varying by more than 0,98 t_B probably are different. (The 95 % confidence levels means that an observer would be correct 19 times out of 20 to accept these alternatives.)

[c] t_B = 6,0 for the purpose of this European Standard means: no penetration. t_B = 6,0 is the maximum achievable value.

EN 13795:2011+A1:2013

Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels

Clause	Requirements - Test	Result - Remark	Verdict

Table 2 — Characteristics to be evaluated and performance requirements for surgical drapes

Characteristic	Test method (for references, see Clause 2)	Unit	Requirement			
			Standard performance		High performance	
			Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration — Dry	EN ISO 22612	CFU	Not required	≤ 300 [a]	Not required	≤ 300 [a]
Resistance to microbial penetration — Wet	EN ISO 22610	I_b	≥ 2,8 [b]	Not required	6,0 [b,c]	Not required
Cleanliness — Microbial	EN ISO 11737-1	CFU/ 100 cm²	≤ 300	≤ 300	≤ 300	≤ 300
Cleanliness — Particulate matter	EN ISO 9073-10	IPM	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5
Linting	EN ISO 9073-10	lg_{10} (lint count)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0
Resistance to liquid penetration	EN 20811	cm H_2O	≥ 30	≥ 10	≥ 100	≥ 10
Bursting strength — Dry	EN ISO 13938-1	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength — Wet	EN ISO 13938-1	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength — Dry	EN 29073-3	N	≥ 15	≥ 15	≥ 20	≥ 20
Tensile strength — Wet	EN 29073-3	N	≥ 15	Not required	≥ 20	Not required

[a] Test conditions: challenge concentration 10^6 CFU/g talc, and 30 min vibration time.

[b] The Least Significant Difference (LSD) for I_b when estimated using EN ISO 22610, was found to be 0,98 at the 95 % confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. Thus materials varying by up to 0,96 I_b are probably not different; materials varying by more than 0,98 I_b probably are different. (The 95 % confidence levels means that an observer would be correct 19 times out of 20 to accept these alternatives.)

[c] I_b = 6,0 for the purpose of this European Standard means: no penetration. I_b = 6,0 is the maximum achievable value.

Table 3 — Characteristics to be evaluated and performance requirements for clean air suits

Characteristic	Test method (for references, see Clause 2)	Unit	Requirement [b]
Resistance to microbial penetration — Dry	EN ISO 22612	CFU	≤ 300 [a]
Cleanliness — Microbial	EN ISO 11737-1	CFU/ 100 cm²	≤ 300
Cleanliness — Particulate matter	EN ISO 9073-10	IPM	≤ 3,5
Linting	EN ISO 9073-10	lg_{10} (lint count)	≤ 4,0
Bursting strength — Dry	EN ISO 13938-1	kPa	≥ 40
Tensile strength — Dry	EN 29073-3	N	≥ 20

[a] Test conditions: challenge concentration 10^6 CFU/g talc, and 30 min vibration time.

[b] Performance requirements apply for all products areas of clean air suits

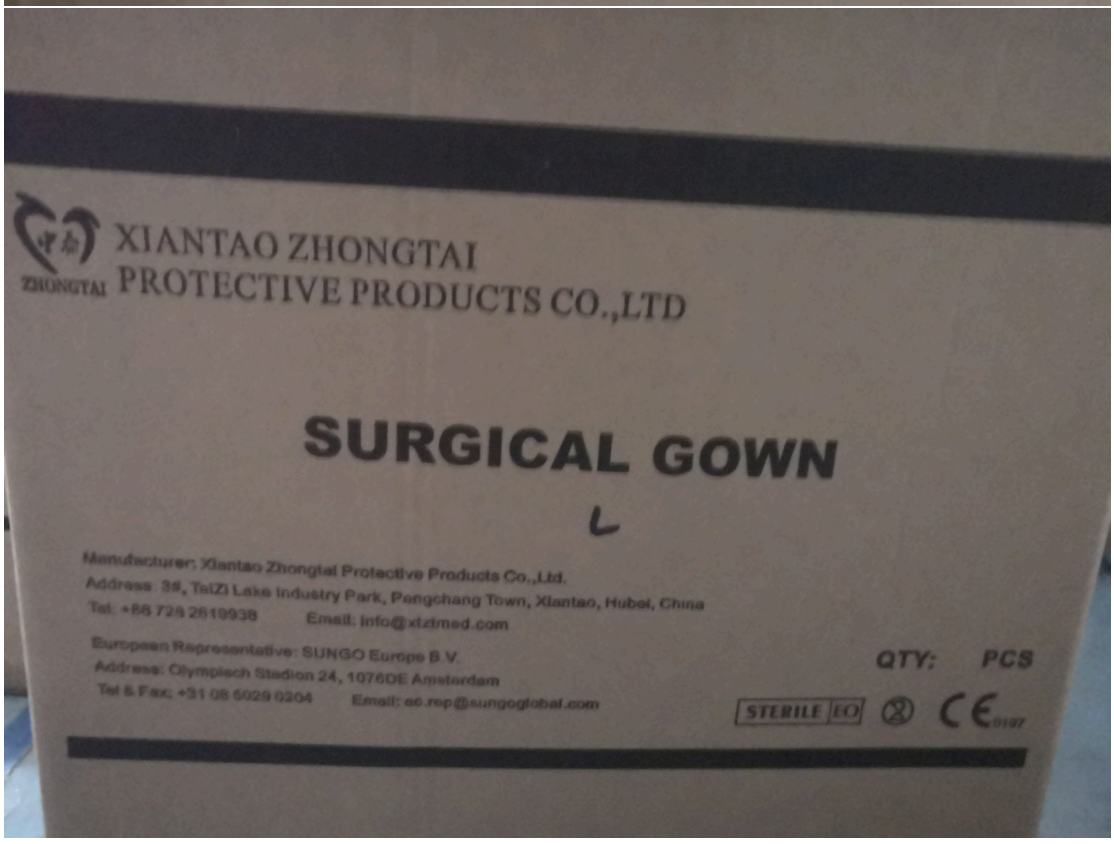
5	**Testing**		**P**
5.1	Testing for evaluation of the performance of products shall be done according to the test methods specified in Annex B. All test results and test conditions shall be recorded and retained.		**P**
5.2	Testing shall be performed on the finished product. If the product is to be used after sterilisation, testing shall be performed on products after sterilisation with the exception of microbial cleanliness. Testing shall include potential weak spots.		**P**
5.3	During manufacture and processing, testing shall be conducted according to the requirements of the manufacturer's and processor's quality system.		**P**

EN 13795:2011+A1:2013 Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels			
Clause	Requirements - Test	Result - Remark	Verdict
5.4	Alternative test methods for monitoring may be used provided that they are validated and address the same characteristic and that the results have been shown to correlate with the test methods given in this European Standard.		P
6	**Manufacturing and processing requirements**		P
6.1	The manufacturer and processor shall document that the requirements set down in this European Standard are met and that the fitness for the intended purpose has been established for each use, both for single-use and reusable medical devices.		P
6.2	**Validated manufacturing and processing procedures shall be used.**		P
6.2.1	A manufacturing and processing specification shall be designed and validated for the product, including visual and hygienic cleanliness		P
6.2.2	The validation shall include all steps of manufacture and processing.		P
6.2.3	The frequency of revalidation shall be determined during validation and shall be reassessed after any change of manufacturing or processing that could materially affect the product		P
6.2.4	The key manufacturing and processing variables shall be identified, monitored and recorded. The type and frequency of routine monitoring shall be documented.		P
6.3	During manufacturing and processing, the control of decontamination and disinfecting procedures and the traceability of sterilisation shall be maintained.		P
7	**Information to be supplied by the manufacturer or processor**		P
7.1	In addition to the information to be supplied according to the Medical Device Directive 93/42/EEC, if the manufacturer or processor differentiates between critical and less critical areas of the product, he/she shall supply information to identify them.		P
7.2	The following additional information shall be supplied on request:		P
	a) the identity or information on the test methods used; b) the results of testing and test conditions for the characteristics given in Tables 1, 2 and 3 in Clause 4.		P

****** End of report ******

ZHONGTAI

手术衣包装 （Package）



ZHONGTAI


XIANTAO ZHONGTAI
PROTECTIVE PRODUCTS CO.,LTD
G.W.: 7.6KG
N.W.: 6.8KG
MEAS: 44*29*47CM
LOT ZT-200406-1
04/2020
04/2023
MADE IN CHINA