

1. Full details of the factory
Business license:



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年度报告

国家市场监督管理总局监制

BMIT
BEST MEDICAL INNOVATIONS

Medical device production license

第一类医疗器械生产备案凭证

备案编号: 鲁济食药监械生产备20140035号

企业名称	济南尚润通达复合材料有限公司		
住所	山东黄河经济开发区		
生产地址	山东黄河经济开发区		
法定代表人	杨向秀	企业负责人	张兴秀
生产范围	I类: 6854 医用冷疗、低温、冷藏设备及器具 6864 医用卫生材料及敷料		
生产产品列表			
产品名称	产品备案号	登记日期	备注
冷敷理疗贴	鲁济械备20160133号	2016-10-19	与2014年5月30日国家食品药品监督管理总局公布2014年第8号《关于第一类医疗器械产品目录表》一致。
医用冷敷贴	鲁济械备20160124号	2016-09-30	与2014年5月30日国家食品药品监督管理总局公布2014年第8号《关于第一类医疗器械产品目录表》一致。
关节冷敷贴	鲁济械备20140186号	2014-10-15	
护腿退热贴	鲁济械备20140187号	2014-10-15	
肩部冷敷贴	鲁济械备20140188号	2014-10-15	
颈部冷敷贴	鲁济械备20140189号	2014-10-15	
颈肩腰腿冷敷贴	鲁济械备20140190号	2014-10-15	
尚润系列退热贴	鲁济械备20140193号	2014-10-15	
腿部冷敷贴	鲁济械备20140194号	2014-10-15	
眼部冷疗贴	鲁济械备20140195号	2014-10-15	
腰部冷敷贴	鲁济械备20140196号	2014-10-15	
医用创可贴	鲁济械备20140197号	2014-10-15	
医用冷敷走珠器	鲁济械备20140198号	2014-10-15	
医用退热走珠器	鲁济械备20140199号	2014-10-15	
尚润冷疗贴	鲁济械备20140192号	2014-10-15	
感冒退热贴	鲁济械备20140185号	2014-10-15	
尚润冷敷贴	鲁济械备20140191号	2014-10-13	



Quality management system certificate:



CERTIFICATE

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 24720Q10022R0S-1

This is to certify that

Jinan Shangrun Tongda Composite Material Co., Ltd.

Organization Code: 913701266648775935

Registration Add.: Shanghe Economic Development Zone, Jinan City, Shandong, P.R.China

Certification Add.: Shanghe Economic Development Zone, Jinan City, Shandong, P.R.China

is in conformity with:

GB/T 19001-2016/ISO 9001:2015

This certificate is covering the following scope:

The production of disinfectant products (75% alcohol disinfectant and hand washing gel disinfectant) within the qualification scope, medical hygienic materials and dressings (plasters products), disinfectant products, 75% alcohol disinfectants, hand gel disinfectants, daily protective masks, medical hygienic materials and dressings (plaster products), and daily protective products within the qualification scope. Production of mask

Issue Date: 2020-04-02

Expiry Date: 2023-04-01

Registration No.: SDCB-2020-0008

于志忠



GB/T 19001



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C210-M

Shandong ChengBiao Certification Technology Co.,Ltd.

Registration Add: Room 407 Jiaxin Business Building, No.154, Huayuan Road, Licheng District, Jinan City, Shandong, P.R. China

Website: [Http://www.sdcbrz.com](http://www.sdcbrz.com)



Registration Form for foreign trade operators

对外贸易经营者备案登记表

备案登记表编号: 04557206

统一社会信用代码: 913701266648775935
进出口企业代码: _____

经营者中文名称	济南尚润通达复合材料有限公司		
经营者英文名称	Jinan Shangrun Tongda Composite Material Co., Ltd.		
组织机构代码	_____	经营者类型 (由备案登记机关填写)	有限责任公司
住 所	山东省济南市商河县经济开发区		
经营场所 (中文)	山东省济南市商河县经济开发区		
经营场所 (英文)	Economic Development Zone of Shanghe County, Jinan City, Shandong Province		
联系电话	13156115757	联系传真	_____
邮政编码	251600	电子邮箱	774505807@qq.com
工商登记注册日期	2007-11-9	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	杨向秀	有效证件号	372826198005257825
注册资金	贰仟伍佰万元		(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/ 个体工商户负责人姓名	_____	有效证件号	_____
企业资产/个人财产	_____		(折美元)

备注	_____
----	-------

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户负责人签字、盖章。



2020

年 月 日



中华人民共和国商务部

MINISTRY OF COMMERCE OF THE PEOPLE'S REPUBLIC OF CHINA

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中国医药保健品进出口商会

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动态更新：取得国外标准认证或注册的医疗器械生产企业清单

2020年06月01日 中国医药保健品进出口商会

分享

6月1日，取得国外标准认证或注册的医疗器械生产企业清单继续更新，其中，医用口罩清单新增120家企业，医用防护用品清单新增11家企业，呼吸机清单新增1家企业，红外体温计清单新增2家企业，新型冠状病毒检测试剂清单新增26家企业。

取得国外标准认证或注册的医疗器械生产企业清单

动态更新：2020年6月1日 下载

Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries			
序号	生产企业	统一社会信用代码	国外注册认证情况
一、	医用口罩 Medical Face Masks		
	Nanchang Kanghua Health Materials Co.,Ltd		
496	南昌翔医医疗器械有限公司 Nanchang Xiangyi Medical Equipment Co., Ltd.	91360124731978002P	欧盟CE
497	新余市诺安医疗器械有限公司 Xinyu Nuonan Medical Equipment Co., Ltd.	91360521MA394NM85L	欧盟CE
498	济南尚润通达复合材料有限公司 Jinan Shangrun Tongda Composite Material Co.,Ltd.	913701266648775935	欧盟CE
499	青岛海诺生物工程有限公司 Qingdao Hainuo Biological Engineering Co., Ltd.	33702657180717488	欧盟CE
500	青岛酷特智能股份有限公司 Qingdao Kutesmart Co., Ltd.	91370200667884653Y	欧盟CE
501	山东国汇新材料有限公司 Shandong Guohui NEW Materials Co., Ltd.	9137152389931278630	欧盟CE
502	威海鸿宇无纺布制品有限公司	91371000699692898J	欧盟CE

EC Deklaracja zgodności

Manufacturer:

Jinan Shangrun Tongda Composite Material Co., Ltd.
Shanghe Economic Development Zone, Jinan City,
Shandong Province, China
Scarlett Liu
Tel: 86 531 58773122
E-mail: 2597875051@qq.com

whose single Authorized EU-Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMDI: DE/0000047791
Lin Sun
Tel: 0049-1715605732
E-mail: info.m@luxuslw.de



We, the manufacturer, herewith declare that the products

Name: Disposable medical mask
Type: NON-STERILE
Model: 17.5cm X 9.5cm

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of Jinan Shangrun Tongda Composite Material Co., Ltd.
Shanghe Economic Development Zone, Jinan City, Shandong Province, China

For and on behalf of
Jinan Shangrun Tongda Composite Material Co., Ltd.
济南尚润通达复合材料有限公司

Place, date

Apr. 7th, 2020

Legally binding signature, Function

Authorized Signature(s)

EC Declaration of Conformity

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority	
Code DE/CA20	
Bezeichnung / Name Bezirksregierung Düsseldorf, Dezernat 24	
Staat / State Deutschland	Land / Federal state Nordrhein-Westfalen
Ort / City Düsseldorf	Postleitzahl / Postal code 40474
Straße, Haus-Nr. / Street, house no. Cecilienallee 2	
Telefon / Phone +49-211-4750	Telefax / Fax +49-211-4752671
E-Mail / E-mail dez24.mpg@brd.nrw.de	
Anzeige / Notification	
Registrierdatum bei der zuständigen Behörde Registration date at competent authority 16.04.2020	Registrierungsnummer / Registration number DE/CA20/01-Luxuslebenswelt-181/20
Typ der Anzeige / Notification type <input checked="" type="checkbox"/> Erstanzeige / Initial notification <input type="checkbox"/> Änderungsanzeige / Notification of change <input type="checkbox"/> Widerrufsanzeige / Notification of withdrawal	
Frühere Registrierungsnummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn	
Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG <input type="checkbox"/> Hersteller / Manufacturer <input checked="" type="checkbox"/> Bevollmächtigter / Authorised Representative <input type="checkbox"/> Einführer / Importer <input type="checkbox"/> Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG <input type="checkbox"/> Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV <input type="checkbox"/> Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG	

Anzeigender / Reporting organisation (person)	
Code DE/0000047791	
Bezeichnung / Name Luxus Lebenswelt GmbH	
Staat / State Deutschland	Land / Federal state Nordrhein-Westfalen
Ort / City Willich	Postleitzahl / Postal code 47877
Straße, Haus-Nr. / Street, house no. Kochstr. 1	
Telefon / Phone 0049-1715605732	Telefax / Fax
E-Mail / E-mail info.m@luxuslw.de	

Hersteller / Manufacturer	
Bezeichnung / Name Jinan Shangrun Tongda Composite Material Co., Ltd.	
Staat / State CN	
Ort / City Jinan City	Postleitzahl / Postal code 251600
Straße, Haus-Nr. / Street, house no. No.26, Kaiyuan Road, Shanghe Economic Development Zone, Jinan City, Shandong Province	
Telefon / Phone 0086-531-58773356	Telefax / Fax
E-Mail / E-mail	

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG	
Bezeichnung / Name Lin Sun	
Staat / State Deutschland	Land / Federal state Nordrhein-Westfalen
Ort / City Willich	Postleitzahl / Postal code 47877
Straße, Haus-Nr. / Street, house no. Kochstr. 1	
Telefon / Phone 0049-1715605732	Telefax / Fax
E-Mail / E-mail info.m@luxuslw.de	

Vertreter / Deputy (optional)	
Bezeichnung / Name	
Telefon / Phone	Telefax / Fax
E-Mail / E-mail	
<input checked="" type="checkbox"/> Erstanzeige / Initial notification <input type="checkbox"/> Änderungsanzeige / Notification of change	



Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
Klasse / Class	<input checked="" type="checkbox"/> I <input type="checkbox"/> I - steril / sterile <input type="checkbox"/> I - mit Messfunktion / with measuring function <input type="checkbox"/> I - steril und mit Messfunktion / sterile and with measuring function <input type="checkbox"/> IIa <input type="checkbox"/> IIb <input type="checkbox"/> III <input type="checkbox"/> III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012 <input type="checkbox"/> Aktives implantierbares Medizinprodukt / Active implantable medical device <input type="checkbox"/> Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012
App (Software auf mobilen Endgeräten)	<input type="checkbox"/> ja / yes <input checked="" type="checkbox"/> nein / no
Nummer(n) der Bescheinigung(en) / Certificate number(s)	
Handelsname des Produktes / Trade name of the device	Disposable Medical Mask
Produktbezeichnung / Name of device	Disposable Medical Mask
Nomenklaturcode / Nomenclature code	15-230
Nomenklaturbezeichnung / Nomenclature term	Maske, sonstige
Kategoriecode / Category code	10
Kategorie / Category	Produkte zum Einmalgebrauch
Kurzbeschreibung deutsch / German short description	Es wird verwendet, um Mund, Nase und Kiefer des Benutzers zu bedecken. Es wird in normalen medizinischen Umgebungen verwendet, um Mund und Nasenhöhle zu tragen und das Ausatmen oder Versprühen von Schadstoffen zu verhindern.
Kurzbeschreibung englisch / English short description	It is used to cover the user's mouth, nose, and jaw. It is used in ordinary medical environments to wear and block the mouth and nasal cavity from exhaling or spraying pollutants.

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
<input type="checkbox"/>	Semikritische Medizinprodukte / Semicritical medical devices <input type="checkbox"/> Gruppe A / Group A <input type="checkbox"/> Gruppe B / Group B
<input type="checkbox"/>	Kritische Medizinprodukte / Critical medical devices <input type="checkbox"/> Gruppe A / Group A <input type="checkbox"/> Gruppe B / Group B <input type="checkbox"/> Gruppe C / Group C Nummer der Bescheinigung / Certificate number
<input type="checkbox"/>	Sterilisationsverfahren / Sterilisation procedures <input type="checkbox"/> Dampfsterilisation / Steam sterilisation <input type="checkbox"/> Gassterilisation / Gas sterilisation <input type="checkbox"/> Strahlensterilisation / Radiation sterilisation <input type="checkbox"/> andere / others Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
 I affirm that the information given above is correct to the best of my knowledge.

Ort
City

Willich

Datum
Date

2020-04-09

Name

Lin Sun

BEST MEDICAL INNOVATIONS

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority	
Bearbeiter / Person responsible Frau Nadine Schlingmeier	Telefon / Phone 0211-475-3853



Registration Notification

Reference Number: JH-ERA-20662V00

Issued Date: April 24, 2020

This Verification will be automatically void if the Notification is rejected by the EU Authorities or upon termination of the EAR.

This is certified that, According to Medical Device 93/42/EEC(MDD), we accepted the appointment to be the Authorized European Representative for products which listed in the attached agreement between below manufacturer and Luxus Lebenswelt GmbH.

Manufacturer: Jinan Shangrun Tongda Composite Material Co., Ltd.

Address: No.26, Kaiyuan Road, Shanghe Economic Development Zone, Jinan City, Shandong Province, China

The Manufacturer declared that the Medical Device complies with de Directive including all essential requirements.

According to Medical Device 93/42/EEC(MDD), the European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011, the German Competent Authority is notified of the Manufacturer's Medical Devices and has allocated registration numbers shown in:

Disposable Medical Mask
Nomenclature code: 15-230
Registration Number: DE/CA20/01-Luxuslebenswelt-181/20

Where the manufacturer affixes the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) and standards have and continue to be met.

Luxus Lebenswelt GmbH

Kochstr. 1, 47877, Willich, Germany.
info.m@luxuslw.de

CE marking to the product listed they must ensure that e
e EU directive(s) and standards have and continue to t

For and on behalf of
LUXUS LEBENSWELT GMBH
Kochstr. 1, 47877 Willich, Germany



Authorized Signature:
Simon Qian

Only used for EU Representative agreements

EU Representative Agreement

Document Number: JH-ERA-20662V00

This agreement will be valid for 1 years from 2020.04.2 to 2021.04.1. Part A could choose to renew the agreement by then, otherwise this agreement will be terminated automatically. 此合同有效期为1年, 自2020年04月2日至2021年04月1日。到期后由甲方选择续约或合同自动失效。

Part A (甲方)	
Name(名称):	Jinan Shangrun Tongda Composite Material Co., Ltd.
Add(地址):	No.26, Kaiyuan Road, Shanghe Economic Development Zone, Jinan City, Shandong Province, China,
Zip Code(邮编):	251600
Contact Person(联系人):	Scarlett Liul
Tel/Fax(联系电话/传真):	0086-531-58773122
E-mail(邮箱):	75169092@qq.com
Party B (乙方)	
Name(名称):	Luxus Lebenswelt GmbH
Add(地址):	Kochstr 1, 47877, Willich, Germany
DIMDI Code:	DE/0000047791
Tax Number:	DE305829099
Contact Person:	Lin Sun
Tel/Fax:	0049-1715605732
E-mail:	info.m@luxuslw.de
Competent authority(主管当局信息)	
Name	Bezirksregierung Düsseldorf, Nordrhein-Westfalen
Federal state	Nordrhein-Westfalen
City	Düsseldorf
Postal code	40474
Street, house no.	Cecilienallee 2
Phone/Fax	+49-211-4750 / +49-211-4752671
E-mail	dez24.mpg@brd.nrw.de

Party A hereby appoints Party B as the authorized European Representative for their Medical Device with CE mark, Party B accepts the appointment to be the authorized European Representative for Party A in the market of European Union (E.U), EEA and Switzerland, Turkey. Both parties enter this agreement as follow, the appointed product categories set out in below form:

甲方任命乙方为CE医疗产品欧盟授权代表, 乙方接受甲方任命, 为甲方在欧盟, EEA、瑞士、和土耳其市场的CE医疗产品授权代表, 双方签署下列协议, 委托的产品类别见下表:

No.	Product Name/产品名称	Models/型号	Classification/分类
1	Disposable Medical Mask		I

For use
Jinan
济南

Foran
LL
Kc
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(



I. Obligations and Liabilities of Party A

甲方职责和义务

1. Party A assures to provide the updated technical files of each product category with CE mark to Party B. If Party A can not provide the required technical file to Party B within 30 days after approval of CE certification or before using CE mark for "self declaration" products, this agreement will be terminated automatically. Party A should take on any aftereffect by itself. The technical files should be the electronic copy (PDF/WORD/JPG/ vision), the written copy would be submitted if required by the competent authority. Detail of the requirements of the submitted files as following:

甲方确保在认证结束后向乙方提供每一大类带CE标志产品的、最新的技术文档。如果甲方在认证结束取得证书之后的30天内，或者“自我声明”产品在使用CE标记之前，仍然没有提供给乙方符合要求的CE技术文档的，本协议自动失效。甲方承担由此而引起的所有后果。甲方必需提交电子文件，文件可以是PDF/WORD/JPG/格式的任何一种。书面文件只有在欧盟当局需要审核时才提交乙方。所提交文件内容的要求如下：

- (i) Declaration of conformity, 符合性声明
- (ii) Copy of the label, packaging and instructions for use (in all languages requested by the countries where the device is marketed), 标签、包装、说明书副本（所有上市国家要求的语言的版本）
- (iii) Notified Body certification (where relevant), 公告机构证书（适用时）
- (iv) Post market surveillance process and data, vigilance reports and complaints, processes and data, 上市后监督过程和记录、警戒报告及投诉、处理和验证
- (v) Technical documentation relevant to market surveillance investigation being undertaken by the Member State, 欧盟成员国上市监督调查有关的技术文件
- (vi) Relevant clinical data / notification, 相关的临床数据/通知
- (vii) Details of any distributors / suppliers putting the CE-marked devices on the market, 经销甲方CE标志医疗器械的经销商/供应商名单
- (viii) Incident reports and corrective actions taken, 事故报告及采取的纠正措施

2. Before each product listed in this agreement is placed into the EU market, Party A must notify Party B and provide Party B with product labeling, updated and details of any distributors / suppliers in EU, otherwise this agreement will be terminated automatically. Party A should take on any aftereffect by itself.

本协议所涉及的每个产品在投放到欧盟市场之前，甲方必须通知乙方，并且应向乙方提供最新的产品标签文件和经销商/供应商的信息。如果甲方没有做到以上任何一项，本协议将自动失效。甲方承担由此而引起的所有后果。

3. If there are any changes of products and update of technical file, Party A shall notify Party B with change notification in electronic copy as soon as possible. Party A shall send relevant information to Party B's email listed as below within one week upon changing information: info.m@luxusw.de. 产品如有改变，技术文件如有更新，甲方应向乙方提供最新产品每一类之内以电子附件的形式将相关信息发送到乙方以下电子邮箱：info.m@luxusw.de.

4. If any accident/near accident of products(including any serious adverse event during clinical investigation in premarket stage)(see clause A1.5 e of "Guideline for Authorized Representatives(MEDDEV 2.5/10)(January 2012)") happens within boundary of E.U.,EEA and Switzerland, Turkey, Party A shall help Party B to investigate the reason in time, and complete the initial report together with Party B. Party A shall present the investigation result and final report to Party B according to MDD 93/42/EEC (MDD products) /IVDD 98/79/EC (IVDD products) and the Guidance of vigilance system. If the accident of the product happens out of E.U., Party A shall

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notify Party B as soon as possible, and Part B should make decision whether to report to competent authority or not.

If the above mentioned accident/near accident of products was known by Party A at first, Party A must send notification to the email of Party B as stipulated in Article 2 hereof in two calendar days and provide the complete report of the investigation, analysis and disposal result of the accident/near accident to Party B by E-mail or other effective means in writing within one week after relevant accident happened.

如果产品在欧盟境内及 EEA 和瑞士、土耳其之发生事故或者准事故（包括在产品前的临床调查阶段发生的严重不良事件）详见“Guideline for Authorized Representatives (MEDDEV 2.5/10) (2012 年 1 月)”，甲方应及时配合乙方调查原因，并向乙方一起负责完成初始报告。甲方应在《欧洲共同体理事会法令》按 MDD 93/42/EEC (MDD 产品) 或 IVDD 98/79/EC (IVDD 产品) 和《警戒系统指南》规定的时间内向乙方报告调查结果和最终报告。如带 CE 标志的产品，其事故、准事故发生在欧盟境外，甲方应及时告知乙方，并向乙方交代是否向主管当局报告。

如果上述事故、准事故是通过甲方渠道发现获得的，甲方应立即在两个自然日内以电子邮件形式发送至上述第 2 条中的电子邮箱中；并需要对事故、准事故的原因、分析和处理结果的报告，用电子邮件或书面方式在相关事件产生一周内通知乙方。

5. Party A shall be responsible for any business dispute related to their product problems, such as medical accidents or claims for compensation concerning quality that arise after sale. Party B shall assist Party A to handle the dispute in accordance with the authorization of Party A. All the expenses occurred outside the china mainland during Party B's handling of the accident shall be borne by Party A. Party A should pay all of the cost of the traffic and other allowance for Party B's employee or advisor in the china mainland for the need of investigation, analysis and disposal of the accident. Party B is entitled to require Party A to pay in advance. Before Party B receives such payment Party B is entitled to refuse to pay on behalf of Party A or take relevant measures.

甲方应对销售后发生的与其产品相关的医疗事故或赔偿索赔等业务的处理负责。乙方根据甲方的授权，协助甲方联络处理。在事故处理中，乙方需要在境外支付的费用，经甲方确认后由甲方承担。如果由于取证、取证核算诉讼、差旅和翻译等费用，乙方有权向甲方追讨其在处理业务工作的食宿、交通费实际支出的费用，由甲方承担。乙方可以要求甲方支付前述的费用，在该费用到账到达乙方指定账户之前，乙方有权拒绝代为履行或者收取相关费用。

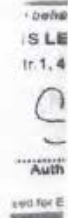
6. Party A should keep the complete sales list of all of the products exporting to any area of E.U, EEA and Switzerland (including the OEM products) by electronic documents in English at least 5 years, in order to be provided by Party B for use being to be transferred or presented to the relevant competent authorities of E.U, EEA and Switzerland. Party A ensures the accuracy and the validity of the data.

甲方应向欧盟地区及 EEA 和瑞士、土耳其之所有产品的销售清单（包括 OEM 的销售清单），在产品停产后至至少五年期间，必须以英文、电子文档形式保留完整无缺，以备乙方随时用于欧盟及 EEA 和瑞士之官方的调查。乙方有权追讨的数据其准确性、真实性负责。

7. Party A must notice Party B the complaint record and the result of disposal on the accident of products immediately, and Party A should save, transfer, check-up any of the record according to the 5th article on the above.

甲方针对客户/用户的故事或者准事故的投诉、抱怨记录和处理结果，除了应该及时通知乙方以外，所有记录的保存、调用、检查，按照上述第 5 条条款办理。

8. Party A should appoint one persons as the primacy linkman who connect with Party B and deal with the normal daily grind according to this agreement. Information of both Parties' linkman should be written in Page one. The information delivered to the primacy linkman who connect with Party A



by Party B shall be deemed as delivery to Party A and the instruction provided by the primary linkman who connect with Party A shall be deemed as the instruction from Party A.

甲方需指定一人,作为甲、乙双方的第一联络人,该联络人需与乙方共同协调,处理本协议设备或规定范围内的日常工作。双方联络人的联络方式记录在本协议的第一页。乙方发送给甲方联络人的信息视作送达给甲方,甲方联络人给出的相关指示视作甲方给出的指示。

9. Party A shall fully realize the risk of selling its products to EU, EEA and Swiss, Turkey market without product registration to relevant competent authority of E.C. If it caused by Party A, such as delay, admittance or conceal of files submission, Party A should take the aftereffects such as warning, penalty or even the results that the CE certificate will be withdrawn, and the distribution of its products in EU, EEA, and Swiss, Turkey market will be prohibited.

甲方需要充分认识到本企业产品由于延误、迟滞、隐瞒或者隐瞒而造成产品没有登记备案就销售欧盟市场及 EEA 和瑞士、土耳其之必定带来的风险。如果由于甲方的原因,发生产品没有登记备案就进入欧盟及 EEA 和瑞士之市场的,甲方将承担罚款、警告,甚至直至撤销 CE 产品证书和禁止产品进入欧盟市场及 EEA 和瑞士、土耳其之的后果。

10. Party A shall notify of the intention to Party B to carry out a clinical investigation for MDD or AIMDD, and the intention to carry out a performance evaluation for IVDD performed in EU, EEA and Swiss, Turkey.

甲方应通知乙方在欧盟、EEA 和瑞士及土耳其对医疗器械或者在希腊及希腊医疗器械进行临床试验的计划,以及对体外诊断试剂进行性能评估的计划。

11. Party B is released by Party A of any liability relating to the medical devices manufactured by Party A.

甲方承诺乙方不对甲方生产的医疗器械的索赔承担任何责任。

12. Party A will be fully responsible for the performance of its products and will hold Party B harmless against any liability claim arising from the use of the products manufactured by Party A.

甲方为其产品性能承担全部责任,无论何时乙方不会因甲方生产的产品在使用过程中产生的任何责任索赔而承担责任。

13. Any liabilities for damage to any third party attributed to causes stipulated herein provided by Party B, Party A shall bear all liabilities for damage and undertake to exempt any responsibilities of Party B to any third party. If it is required for Party B to employ any expert and counsel, especially to employ legal counsel to provide consultation and legal advice, Party A shall bear all relevant fees caused by the employment and pay such fees in advance upon request of Party B.

如果乙方因提供本协议中规定的原因而产生的任何第三方损害赔偿责任,甲方应承担全部责任,并免除乙方对第三方的责任。如果乙方因此需要聘请专家和顾问,特别是法律顾问提供咨询和法律服务,甲方应承担乙方因此而产生的相关合同费用,乙方有权要求甲方预付相关费用。

II. Obligations and Liabilities of Party B

乙方的职责和义务

1. About the register for Party A's products with CE mark to relevant competent authority of E.C., Party A shall apply it in written to Party B and supply all the files and forms needed. Party B shall review it within 7 working days, and submit to competent authority of the country in which Party B is located (Germany) within 5 days. If Party A's application is returned/rejected by Party B or the competent authority for the contents of the submitted files, the above schedule will be adjusted accordingly.

If it needs any expenditure by the competent authority, only after getting Party A's approval, then Party A can take on the payment. If Party A's products register fails by Party B's reason, according to Germany/EU relevant laws Party B will be given a warning, penalty and even the qualification of



the European Representative will be revoked

如果甲方已粘贴 CE 标志的产品按欧盟相关规定必须需要办理 CE 产品欧盟登记备案的, 需先由甲方提出申请, 并提供所有符合规定的文件并填写申请表, 经乙方初审认可后, 再乙方负责在 7 个工作日内完成初审, 5 个工作日内提交乙方所在国德国主管当局审核申请登记备案的文件, 但是由于甲方提交文件内容方面的原因被乙方或者当局退回/拒绝的申请, 不在此时间规定之列。

德国主管机构审核上述登记备案如需要收取相关费用的, 需经甲方同意方可由乙方代为支付。如果由于是乙方的原因, 甲方的申请登记备案手续失败而影响企业产品正常进入欧盟市场的, 根据德国/欧盟有关法律法规, 乙方将受到警告、罚款、吊销担任欧盟代表资格的处罚。

- 2. Party B shall reserve technical files of each category of party A's products with CE mark. The technical files shall be reserved for at least ten years after manufacturing of the last batch of products. Once competent authority needs the technical files (including new edition of the technical files which had already registered) of each category of part A's products with CE mark. Party B should send them to competent authority within ten workdays.

乙方应保留甲方每一大类获得 CE 标志产品的技术文档, 该文档至少保存至最后一批产品出厂后十年。一旦欧盟主管当局需要获得 CE 标识产品的技术文件(含已备案的技术文件的新版本), 乙方负责在 10 个工作日内递交欧盟主管当局。

- 3. Upon receiving the CE technique files, Party B shall give a electronic receipt to Party A within 3 working days. It's the evidence that Party B have received all the required files. Party B would not be responsible for the file content. All the documents, such as sales list and complain records are deemed confidential information. Party B have the obligation to send them to competent authority if necessary. Part B should maintain and keep them secret.

乙方收到甲方提供的CE技术文档等文件的3个工作日内, 向甲方出具电子“回执”; 该“回执”仅证明乙方收到甲方的文件, 而不对文件的内容负责。乙方对甲方提供的销售清单、投诉记录等文件, 负责递交欧盟相关机构审阅并负有保管、保密的义务。

- 4. Party B shall notify any information about the products with CE mark within the Boundary of E.C., including any claims of customers and the competition company that produce the same CE marked products, to Party A.

乙方应对有关 CE 产品在欧盟境内的任何消息(包括客户投诉和同类型竞争对手)及时通知甲方。

- 5. If any serious accident of products happen within the Boundary of E.C., Party A within two calendar days of complaint or feedback on Party A's products and assist Party A to execute vigilance system of medical device products, and also make the initial report together with Party A. Party B shall then present the initial report, investigation results and the final report to competent authority of country in which the accidents happen.

如果带有 CE 标志的产品在欧盟境内发生严重事故, 乙方应在收到有关甲方产品的投诉或反馈信息两个自然日内通知甲方, 并在甲方的协助之下调查原因, 同甲方一起负责完成初始报告。乙方负责把完成的初始报告、调查结果和最终报告向事故发生国主管当局提供。

- 6. Party B shall appoint one persons as the primacy linkman whose responsibility is to connect with Party A and deal with the normal daily grind according to this agreement. The information of both Parties' linkman was written in first page of this contract.

乙方需指定一人, 作为甲、乙双方的一线联络人, 主要职责是与甲方共同协调、处理本协议条款规定范围内的日常工作。双方联络人的联络方式记录在本协议的第一页。

- 7. Party B shall assist Party A to comprehending the condition of the same products within boundary of E.U, and send the related information to Party A in time.

材料



乙方协助甲方了解欧盟市场同类产品的情况，并及时反馈给甲方。

8. Party B shall keep all technical files and information of Party A's in confidentiality.

乙方应对甲方技术文档和资料保密。

III. SERVICE FEE 服务费用

Party A shall pay the service fees to Party B separately according to the agreement for the relevant service provided by Party B.

就乙方提供本协议规定的相关服务，应当按照单独约定支付乙方服务费用。

Provided that Party A requires Party B to provide the service beyond scope stipulated herein, both parties shall agree relevant fees separately in writing.

如果甲方需要乙方提供超出本协议规定之外的服务，甲乙双方应当对此另行书面约定相关费用。

IV. Others

1. Written Form Clause 书面形式

Amendments to this Contract shall only be valid when given in writing. The requirement of form may only be waived in writing. Verbal collateral agreements or modifications are not valid.

本意向协议的任何更改与补充均应以书面形式进行。这一规定同样适用于本条款（关于书面形式）的修改。口头协议和口头修改无效。

2. Contract Language 合同语言

This agreement exists in English and Chinese language. The Chinese version is an exact duplicate of the English version.

本协议为中文和英文的对照版本，中文版本和英文版本内容完全一样。

3. Severability clause 可分割性条款

If any provision of this agreement or a provision incorporated herein at a later date is or shall become invalid in whole or in part, or if this agreement or any modification thereof is found to have a gap, this shall not affect the validity of the remaining provisions. It is, however, the express intention of the parties to maintain the validity of the other provisions of the agreement under all circumstances. In place of any invalid provision or to fill a gap, a valid and enforceable provision shall be agreed which most closely corresponds legally and economically to that which the parties intended or would have intended within the meaning and purpose of the agreement and any later modifications, if they had considered this issue when concluding the agreements. If the invalidity of any provision is due to a measure of performance or time (time-limit or date) stated therein, a measure of performance which most closely corresponds to the original measure in a legally admissible way must be agreed for this provision.

如若本协议中的条款或者其补充了现在或者将来无效，其他部分不受其影响，该规定同样也适用于协议内容缺失的情形。但协议双方明确表示，上述可分割性条款是为了确实保证合同其它部分不因合同部分无效而整体无效受到影响。就无效条款和缺失部分，协议双方应当在法律允许的范围内本着最接近原有合同目的，最能达到其共同预期为标准，达成有效的补充规定，以替代该无效条款或者填补协议内容的缺失。

This agreement is subject to the requirement specified in the <EU 93/42/EEC Directive 1998>, <EU 2007/47/EEC Directive 2007>, <EU 98/79/EC Directive 2003> and the <MEDDEV 2.12-1 REV.8 January 2013> Should there be any conflicts between this agreement and <EU 93/42/EEC Directive 1998>, <EU 2007/47/EEC Directive 2007>, <EU 98/79/EC Directive 2003> and the <MEDDEV

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2.12-1 REV.8 January 2013> shall be followed as standards. If the regulation above update or change, Party A and Party B should actively negotiate and communicate to ensure that the requirements of the new regulation are met.

本协议受《欧共体关于医疗器械的 93/42/EEC 指令》、《欧共体关于医疗器械的2007/47/EEC 指令》、《欧共体关于体外诊断医疗器械的90/79/EC 指令》和《医疗器械警戒体系指南》约束。如本协议条款与《指令》或《指南》冲突，以《指令》和《指南》为准。如上述法规发生更新或变更，甲乙双方应积极协商和沟通，确保持续满足新法规的要求。

During the implementation of the agreement, this agreement will be terminated automatically when: 在协议执行期间内，下列日期为本协议的自动终止日期:

(a) The day upon Part A's CE Certificate be withdrawn temporarily, be closed or be recalled by the notified body.

(When the above mentioned things happen, Party A is obligated to accomplish the following processes to avoid the further consequences:

甲方的 CE 证书因事故被发证机构暂时吊销/关闭/收回的。

(以上事实一旦发生，甲方需第一时间配合乙方进行以下善后工作。乙方将承担由于不作为或者作为不当而产生的所有责任。

- Brief statement in written about the reasons why CE Certificate being withdrawn, being closed or being recalled by the notified body. 书面简要说明证书被吊销/关闭/收回的原因。包括更换公告机构的理由。

- Written statement of non-sales if there are no products under the withdrawn, closed or recalled CE Certificate exporting to EU, EEA and Swiss, Turkey market, or if there are products exporting, a written statement of sales would be required with the sales list, risk assessments and the measures and timetable to cover the risk.)

书面确认被取消的CE证书所有相关产品是否已经售出欧盟市场以及EEA和瑞士、土耳其之市场。如果没有，请出具书面申明。如果有，则附上销售清单。同时请书面评估因此可能产生的风险并陈述平方拟采取的预防和纠正措施。

(b) Party A can not provide the required technical file to Party B within 30 days after approval of the CE certification or before using CE mark for self declaration. During 60 days from the date of this agreement terminated, Party A could transact the routine affairs as the authorized European Representative while Party A could appoint new European Representative and change the CE certification. Party B should report the invalid agreement to the notify body for record.

甲方在认证结果取得证书之后的30天内，或者“自我声明”产品在受用CE标记之前，仍然没有提供符合乙方要求的CE技术文件的，本协议自动失效。在本失效之日起的60天内，为了能够方便甲方聘请新的欧盟代表及更改CE证书等相关工作，乙方可以代为继续行使欧盟代表日常事务。乙方应该将与甲方失效的协议信息及时报公告机构备案。

(c) Party A doesn't payoff the service fee according to this agreement and refuse to explain on the deadline.

甲方没有被协议规定的最后期限内付清欧盟代表服务费用，又不作解释的。

No other rights or obligations are applied to Party A or Party B other than specified in this agreement. 除本协议外，甲、乙双方不赋予其他权利和义务。



Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany

PART A:

For and on behalf of
Jinan Shangrun Tongda Composite Material Co., Ltd.
济南尚润通达复合材料有限公司

Signature (签字):
Company Stamp (公章):
Date (日期):

Authorized Signature(s)

PART B: Luxus Lebenswelt GmbH
For and on behalf of

LUXUS LEBENSWELT GMBH
Kochstr. 1, 47877 Willich, Germany

Signature (签字):
Company Stamp (公章):
Date (日期):

Authorized Signature:
Simon Qian

Only used for EU Representative agreements



公司





FDA Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

JINAN SHANGRUN TONGDA COMPOSITE MATERIAL CO. , LTD.

Shanghe Economic Development Zone,

jinan, Shandong, 251600,

CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Owner/Operator Number: 10063110



Device Listing:

Device#	Code	Device Name
D375346	LYU	ACCESSORY, SURGICAL APPAREL (Disposable Protective Face Mask)

ZCQC Services, LLC 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. ZCQC Services, LLC 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. ZCQC Services, LLC 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. ZCQC Services, LLC is not affiliated with the U.S. Food and Drug Administration.



ZCQC Services, LLC

U.S. Food and Drug Administration
Tell: 1-888-INFO-FDA (1-888-463-6332)
Add: 10903 New Hampshire Avenue
Silver Spring, MD 20993
Email: webmail@oc.fda.gov
Website: www.fda.gov

Erangeline

Executive Director
Issued: 17/03/2020
Cert. No.: 20200317001
Expiration Date: 12/31/2020



中国认可
国际互认
检测
TESTING
CNAS L0412

检测报告

(Test Report)

No. GOL32F7V843305L1a

样品名称
(Sample Description)

一次性医用口罩 (非无菌)
Disposable medical mask (NON-STERILE)

委托单位
(Applicant)

济南尚润通达复合材料有限公司
Jinan Shangrun Tongda Composite Material
Co., Ltd.
BEST MEDICAL INNOVATIONS



声明
Statement

1. 本报告无特殊检测专用章, 报告骑缝章和批准人签章无效。
This report is invalid without special seal of inspection, cross-page seal and the approver's signatures.
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If the applicant has any questions about the results, shall provide a written retest application with the original report, and prepay the retest fees to PONY within fifteen days since the approval date (as an exception, it shall be within five days since the date received for the primary agriculture products report).
4. 委托单位办理完以上手续后, 本单位会尽快安排复测, 如果复测结果与异议内容相符, 本单位将退还委托单位的复测费。
After the applicant finishes the procedure mentioned above, PONY shall arrange the retest as soon as possible. If the retest result accords with the applicant dissent, PONY shall refund the retest fees.
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		广州实验室: (020) 89224310
		厦门实验室: (0592) 5680848
		成都实验室: (028) 87702708

检测结果
(Test Results)

No. GOL32F7V843305L1a

第 1 页, 共 3 页 (page 1 of 3)

样品名称 (Sample Description)	一次性医用口罩 (非无菌) Disposable medical mask (NON-STERILE)	样品规格 (Sample Specification)	17.5cm*9.5cm
委托单位 (Applicant)	济南尚润通达复合材料有限公司 Jinan Shangrun Tongda Composite Material Co.,Ltd.	商标 (Trade Mark)	—
到样日期 (Received Date)	2020-06-20	生产日期或批号 (Manufacturing Date or Lot No.)	2020 年 5 月 26 日 20200526001
检测日期 (Test Date)	2020-06-20~2020-07-10	样品等级 (Sample Grade)	—
样品状态 (Sample Status)	正常 Normal	检测类别 (Test Type)	委托检测 Commissioning Test
检测项目 (Test Items)	见下页 See next page	检测环境 (Test Environment)	符合要求 To meet the requirements
检测方法 (Test Methods)	见下页 See next page		
所用主要仪器 (Main Instruments)	口罩颗粒物过滤效率及气流阻力测试仪 等 Respirator particle filtration efficiency and airflow resistance tester etc.		
备注 (Note)	<p>1.型号: 17.5cm×9.5cm Model: 17.5cm×9.5cm 2.生产单位/受检单位: 济南尚润通达复合材料有限公司 Manufacturer/ Tested company: Jinan Shangrun Tongda Composite Material Co.,Ltd. 3.以上样品信息由委托单位提供 The information of sample was provided by the applicant 4.该报告中检测方法由委托单位指定。 The testing methods mentioned in this report were designated by the applicant. 5.此报告替代编号 GOL32F7V843305L1 (2020 年 07 月 06 日签发) 检测报告。 编号 GOL32F7V843305L1 检测报告作废, 不具有任何法律效力, 以此报告为准。2020 年 07 月 10 日 This report replaces test report No. GOL32F7V843305L1 issued on 2020.07.06 and shall prevail. Test report No. GOL32F7V843305L1 is invalid and have no any legal force.2020.07.10</p>		
	编制人 (Edited by)	张剑	
	审核人 (Checked by)	田迎迎	
	批准人 (Approved by)	梅树崇	
	签发日期 (Issued Date)	2020 年 07 月 10 日	

检测结果
(Test Results)

No. GOL32F7V843305L1a

第 2 页, 共 3 页 (page 2 of 3)

序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	检测结果 (Test Result)			检测方法 (Test Method)
1	细菌过滤效率 Bacterial filtration efficiency	%	99.78			BS EN 14683:2019 附录 B Appendix B
			99.48			
			99.66			
			99.70			
			99.61			
2	压力差 Differential pressure	Pa/cm ²	试样编号-测试区域 编号 Test Specimen number-Test area number	每个测试区域的压力差 Differential pressure for each test area	每个试样的平均压差 The averaged differential pressure for each test specimen	BS EN 14683:2019 附录 C Appendix C
			1-1	27.5	30.2	
			1-2	33.0		
			1-3	29.8		
			1-4	27.0		
			1-5	33.6		
			2-1	32.5	31.1	
			2-2	31.7		
			2-3	32.5		
			2-4	29.4		
			2-5	29.2		
			3-1	35.0	31.9	
			3-2	31.1		
			3-3	31.2		
			3-4	34.2		
			3-5	28.1		
			4-1	26.7	30.6	
			4-2	27.6		
			4-3	33.6		
			4-4	30.3		
			4-5	34.9		
			5-1	31.2	32.8	
			5-2	31.8		
			5-3	35.8		
			5-4	35.2		
5-5	29.9					

检测结果
(Test Results)

No. GOL32F7V843305L1a

第 3 页, 共 3 页 (page 3 of 3)

序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	检测结果 (Test Result)	检测方法 (Test Method)
3	抗溅压力 Splash resistance pressure	kPa	32 个试样均 > 16.0 Splash resistance pressure of 32 samples were greater than 16.0	ISO 22609:2004
4	微生物洁净度 Microbial cleanliness	cfu/g	<1	BS EN 14683:2019 附录 D Appendix D
			<1	
			<1	
			<1	

照片 Photo:



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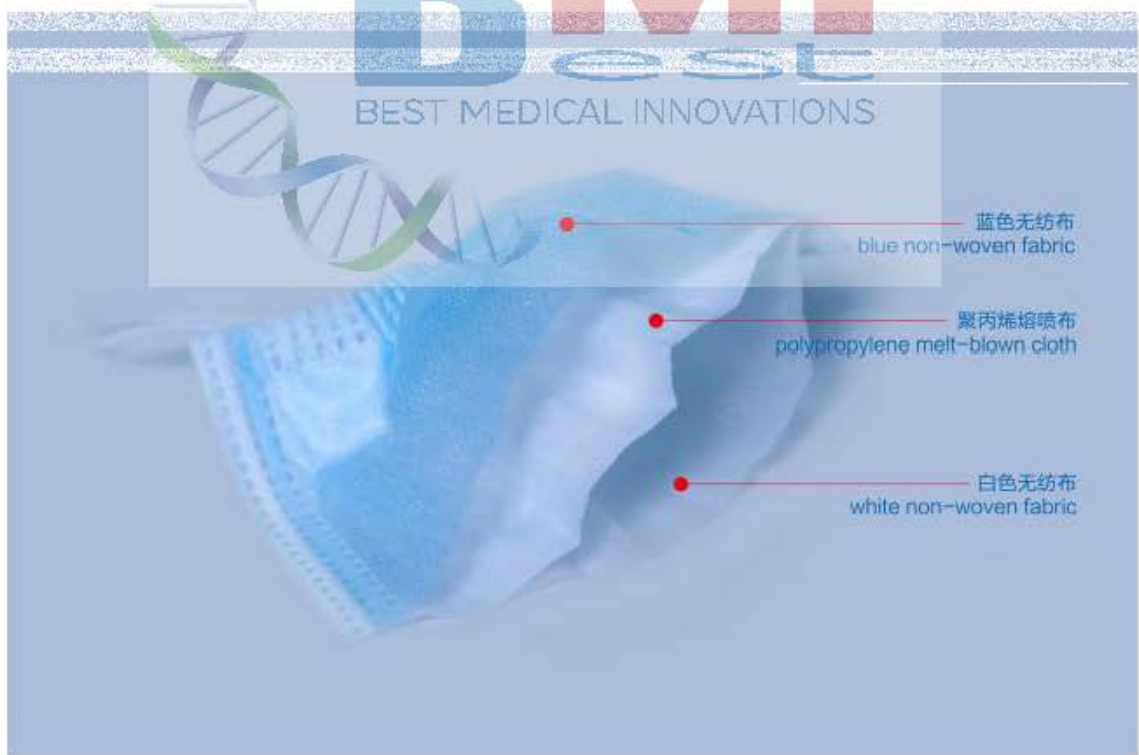
BMI
Best

BEST MEDICAL INNOVATIONS

蓝色无纺布
blue non-woven fabric

聚丙烯熔喷布
polypropylene melt-blown cloth

白色无纺布
white non-woven fabric



一次性医用口罩盒子
尺寸23.5*12.5*20cm



BMI
Best
BEST MEDICAL INNOVATIONS

EN14683:2019 +AC:2019

Product Name: Disposable Medical Mask
Type: NON-STERILE
Model: 17 (Standard)
Composition: The product consists of a mask body & nose clip and a mask band. The mask body is composed of non-woven fabric (inner and outer layers) and polypropylene melt-blown cloth (middle layer). Non-woven polypropylene.
Indication: It is used to cover the user's mouth, nose and eyes and prevent respiratory secretions to avoid self-infection.
Product performance:
Bacterial leakage efficiency (BLE) greater than or equal to 95%.

Warnings:
1. Single use only. Please wear mask
2. Please handle mask from the middle of the
3. Avoid contact with oil, acid, alkali and other
4. Use all time as possible after opening
5. It can not be used in special medical
6. Please do not use. Products labeled with
7. Do not use.

Puri's Health
普瑞益生

DISPOSABLE
MEDICAL MASK
(NON-STERILE)

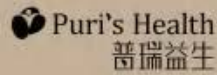


This product consists of a mask body, a nose clip and a mask band. The mask body is composed of non-woven fabric (inner and outer layer) and polypropylene melt-blown cloth (middle layer). Non-sterile, single-use.

100 pieces (pieces/bag = 10)



BIM Best
BEST MEDICAL INNOVATIONS



DISPOSABLE MEDICAL MASK (NON-STERILE)

This product consists of a mask body, a nose clip and a mask band.
The mask body is composed of non-woven fabric (inner and outer layer) and polypropylene melt-blown cloth (middle layer). Non-sterile, single-use.

2000 pieces
50pieces/bag × 2/box × 20/carton



EN14683:2019 +AC:2019

Device name: Disposable Medical Mask
Package: 50pieces/bag × 2/box × 20/carton
Carton Size: 64.5cm × 49cm × 42cm
Shelf Life: 24 Months

Manufacturer: Jinan Shangrun Tongda Composite Material Co., Ltd.
Address: No.26, Kaiyuan Road, Shanghe Economic Development Zone, Jinan City, Shandong Province, China

Storage: The product should be stored in a dry, ventilated and pollution-free area; the temperature should be +40°C-0°C, and the humidity should not be higher than 80%; keep away from fire sources, avoid dust exposure and direct sunlight.

Contact: +86-531-58773356

EC REP
Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany.

Batch No.: 20200501
Manufacture Date: 05/2020
Expiry Date: 05/2022

MADE IN CHINA



一次性医用口罩外箱
尺寸64.5*49*42cm

BMI
Best
BEST MEDICAL INNOVATIONS





Puri's Health
普瑞益生

DISPOSABLE MEDICAL MASK (NON-STERILE)

The product consists of a mask body, a nose clip and a mask band. The mask body is composed of non-woven fabric (inner and outer layer) and polypropylene non-woven cloth (middle layer). Non-sterile, single-use.

2000 pieces
50 pieces/bag * 2 box * 20 carton



DISPOSABLE MEDICAL MASK (NON-STERILE)

The product consists of a mask body, a nose clip and a mask band. The mask body is composed of non-woven fabric (inner and outer layer) and polypropylene non-woven cloth (middle layer). Non-sterile, single-use.

2000 pieces
50 pieces/bag * 2 box * 20 carton

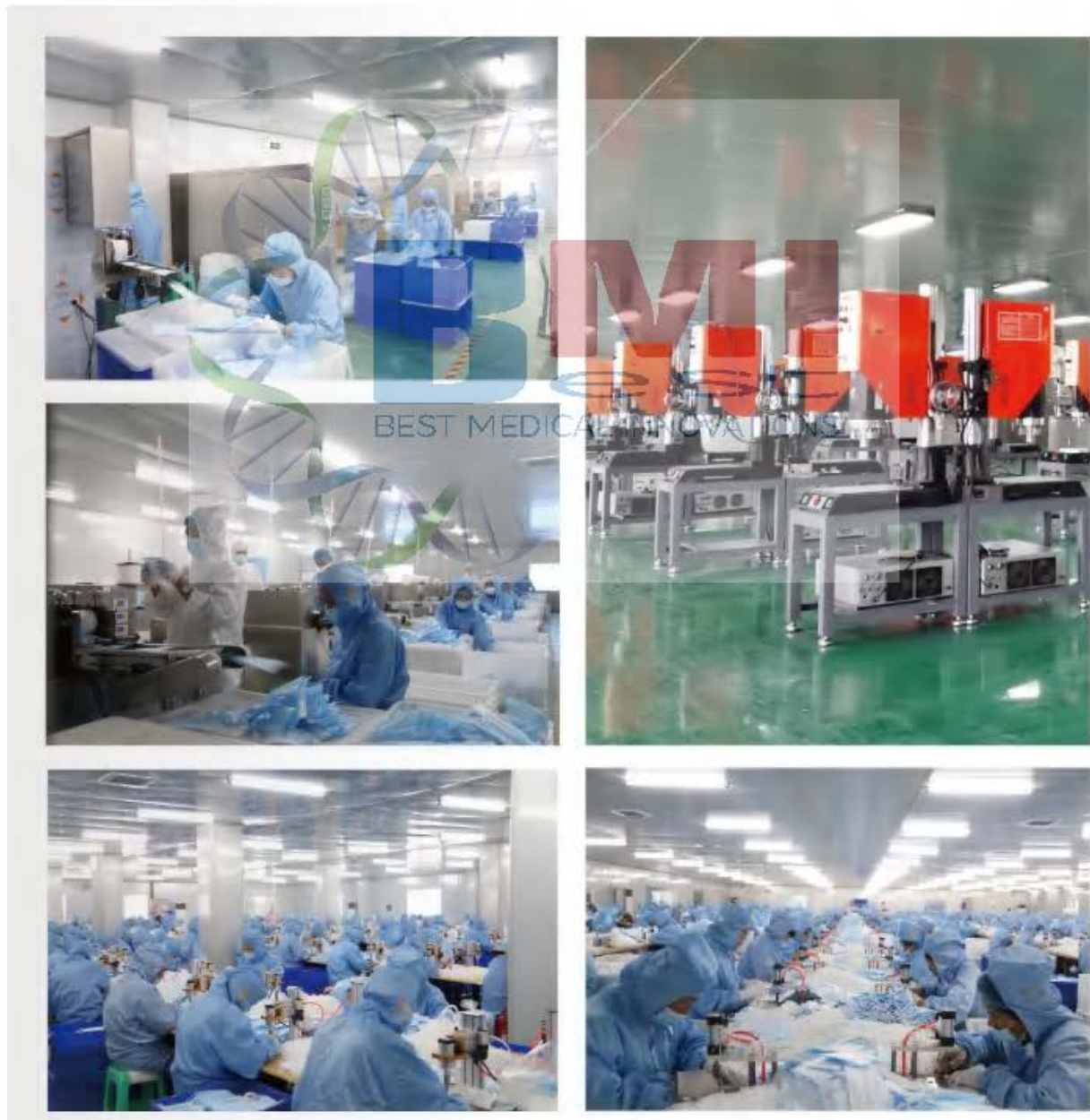


MADE IN CHINA

BEST MEDICAL INNOVATIONS

济南尚润通达复合材料有限公司是一家集防疫物资的研发、生产、销售于一体的高新技术企业。拥有无尘净化车间2万平方，员工3000余人，日产70万片的一次性医用口罩超声机30台，点焊机1000多台，KN95呼吸防护口罩机150台。一次性医用口罩现日产1500万片至2000万片，KN95呼吸防护口罩现日产1000万片以上。

Jinan Shangrun Tongda Composite Material Co., Ltd. is a high-tech enterprise that integrates research and development, production and sales of epidemic prevention materials. It has a dust-free purification workshop of 20000 square meters and more than 3000 employees. 30 sets of disposable medical mask ultrasonic machine with daily output of 700000 pieces, More than 1000 spot welding machines, There are 150 sets of kn95 respirators. Disposable medical masks now produce 15 million to 20 million pieces a day, More than 10 million pieces of Kn95 respirator are produced per day.





• Spot welding workshop 1



• Spot welding workshop 2



• Workshop 1



• Workshop 2



• Workshop 3



• Observation microscope for fiber distribution of meltblown cloth



• Aerosol medium filtration rate detection equipment



• Salt medium filtration rate detection equipment

现有先进的熔喷布过滤检测仪器3台、熔喷布纤维分布观测显微镜1台，严格把关,尚润通达为您的放心选择保驾护航

At present, there are 3 sets of advanced meltblown cloth filter detection instruments. 1 set of fiber distribution observation microscope for meltblown cloth. Strictly control, Shangrun Tongda will escort you for your safety.





“专业制造，专心服务”，尚润通达将以卓越的产品品质谱写企业与社会和谐、健康发展的新篇章。

Professional manufacturing, dedicated service, Shangrun Tongda, with excellent product quality, will usher a new chapter of harmonious and healthy development between enterprise and society.