统一社会信用代码

91440608193550251 9

营业执照

(副 本)(副本号:2-1)

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　佛山市康复医疗设备厂

类　　型　集体所有制

法定代表人　黄伟民

经营范围　生产、销售：III类6864医用卫生材料及敷料，II类6866医用高分子材料及制品（凭有效许可证经营）。制造、加工、修理：轮椅、拐杖、残疾人机动车；加工：塑料，纺织品；货物或技术进出口（国家禁止或涉及行政审批的货物和技术进出口除外）。加工：塑料，纺织品。〓（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。）〓

注册资金　人民币伍拾万元

成立日期　1995年05月30日

经营期限　长期

住　　所　佛山市高明区荷城街道富湾高富一路

登记机关　　2020 年 3 月 18 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn　　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

医疗器械生产许可证

许可证编号：粤食药监械生产许20010139号

企业名称：佛山市康复医疗设备厂

法定代表人：黄伟民

企业负责人：黄伟民

住　　所：佛山市高明区荷城街道富湾高富一路

生产地址：佛山市高明区荷城街道富湾高富一路

生产范围：见医疗器械生产产品登记表

发证部门：广东省食品药品监督管理局

有效期限：至　2020　年　11　月　15　日

发证日期：　2016　年　12　月　01　日

国家食品药品监督管理总局制

医疗器械生产产品登记表

企业名称	佛山市康复医疗设备厂
许可证编号	粤食药监械生产许 20010139 号
许可证有效期限	至 2020 年 11 月 15 日
生产范围	II 类 6864 医用卫生材料及敷料，II 类 6866 医用高分子材料及制品

生产产品列表

序号	产品名称	注册号	登载日期	备注
1	外科纱布敷料	粤械注准 20152640596	2015 年 11 月 16 日	
2	一次性使用医用口罩	粤械注准 20152641443	2016 年 06 月 06 日	
3	一次性使用手术衣	粤械注准 20172641690	2018 年 08 月 08 日	
4	一次性使用无菌导尿包	粤械注准 20172661795	2018 年 08 月 08 日	
5	医用外科口罩	粤械注准 20172641484	2018 年 08 月 08 日	

发证部门（公章）：

2018 年 08 月 08 日

中华人民共和国医疗器械注册证

注册证编号：粤械注准20172641484

注册人名称	佛山市康复医疗设备厂
注册人住所	佛山市高明区荷城街道富湾高富一路
生产地址	佛山市高明区荷城街道富湾高富一路
产品名称	医用外科口罩
型号、规格	型号：挂耳式、绑带式；规格：（18±1）cm×（9.5±0.5）cm
结构及组成	由罩体、口罩带、鼻夹组成。
适用范围	适用于医务人员或相关人员的基本防护，以及在有创操作过程中阻止血液、体液和飞溅物传播的防护。
附　　件	产品技术要求。
其他内容	无
备　　注	原产品注册证号：粤食药监械（准）字2014第2640031号

审批部门：广东省食品药品监督管理局

批准日期：2017年08月03日

有效期至：2022年08月22日

对外贸易经营者备案登记表

统一社会信用代码：91440608193550251 9

备案登记表编号：02477932　　进出口企业代码：——————

经营者中文名称	佛山市康复医疗设备厂		
经营者英文名称	Foshan Kangfu Medical- Facility Factory		
组织机构代码	——	经营者类型（由备案登记机关填写）	集体企业
住　所	广东省佛山市高明区荷城街道富湾镇高富一路		
经营场所（中文）	广东省佛山市高明区荷城街道富湾镇高富一路		
经营场所（英文）	Gaofu 1st Road, Fuwan Town, Hecheng Street, Gaoming District, Foshan City, Guangdong Province		
联系电话	0757-88818892	联系传真	0757-88819028
邮政编码	528500	电子邮箱	347592356@qq.com
工商登记注册日期	1995-5-30	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	黄伟民	有效证件号	440601196510050613
注册资金	伍拾万元	（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	

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。

2020 年 03 月 9 日

备案登记机关签章（佛山高明）

本对外贸易经营者作如下保证：

一、遵守《中华人民共和国对外贸易法》及其配套法规、规章。

二、遵守与进出口贸易相关的海关、外汇、税务、检验检疫、环保、知识产权等中华人民共和国其他法律、法规、规章。

三、遵守中华人民共和国关于核、生物、化学、导弹等各类敏感物项和技术出口管制法规以及其他相关法律、法规、规章，不从事任何危害国家安全和社会公共利益的活动。

四、不伪造、变造、涂改、出租、出借、转让、出卖《对外贸易经营者备案登记表》。

五、在备案登记表中所填写的信息是完整的、准确的、真实的；所提交的所有材料是完整的、准确的、合法的。

六、《对外贸易经营者备案登记表》上填写的任何事项发生变化之日起，30 日内到原备案登记机关办理《对外贸易经营者备案登记表》的变更手续。

以上如有违反，将承担一切法律责任。

对外贸易经营者签字、盖章

2020 年 3 月 20 日

注：1、备案登记表中“组织机构代码”一栏，由企业、组织和取得组织机构代码的个体工商户填写。

2、依法办理工商登记的外国（地区）企业，在经营活动中，承担有限 / 无限责任。依法办理工商登记的个体工商户（独资经营者），在经营活动中，承担无限责任。

3、工商登记营业执照中，如经营范围不包括进口商品的分销业务，备案登记机关应在备注栏中注明“无进口商品分销业务”。

海关进出口货物收发货人备案回执

企业名称	佛山市康复医疗设备厂
统一社会信用代码	91440608193550251 9
海关编码	440695003A
检验检疫备案号	4456200538
有效期	长期

（注册海关）高明海关

（注册日期）2020年04月13日

注册备案专用章

自然人、法人或者非法人组织可通过“中国海关企业进出口信用信息公示平台”（http://credit.customs.gov.cn）或者“互联网+关”（http://online.customs.gov.cn）查询海关公示的企业信息。

European Commission

Declaration of Conformity

Manufacturer: Foshan Kangfu Medical- Facility Factory

Address: Gaofu 1st Road, Fuwan Town, Hecheng Street, Gaoming District, Foshan City, Guangdong Province, 528531, China

EU Authorised Representative:

Osmunda Medical Technology Service GmbH

Address: Von Oppen-Weg 15, 14476 Potsdam, Germany

DIMDI code: DE/0000047267

Device: Surgical medical mask **Model**: Ear hanging type

Classification (MDR, Annex VIII): Class I

Conformity assessment route: ANNEX II+ANNEX III

We herewith declare that the above mentioned product meet the provisions of the following regulation (EU) MDR 2017/745. All supporting documentations are retained under the premises of the manufacturer.

CE

General applicable regulation:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

Standard Applied:

EN ISO 13485:2016	EN ISO 14971:2012	EN 14683:2019 +AC: 2019	BS EN ISO 15223-1:2016
EN ISO 10993-1:2009/AC:2010	EN ISO 10993-5:2009	ISO 10993-10:2010	EN 1041:2008

Place, Date of Issue:

Foshan, 2nd April 2020

Signature:

Xianzhi Huang

Management Representative

Declaration of Conformity

Manufacturer: Foshan Kangfu Medical- Facility Factory

Address: Gaofu 1st Road, Fuwan Town, Hecheng Street, Gaoming District, Foshan City, Guangdong Province, 528531, China

EU Authorised Representative:

Osmunda Medical Technology Service GmbH

Address: Von Oppen-Weg 15, 14476 Potsdam, Germany

DIMDI code: DE/0000047267

Device: Surgical medical mask **Model:** Ear hanging type

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Standard Applied:

EN ISO 13485:2016	EN ISO 14971:2012	EN 14683:2019 +AC: 2019	BS EN ISO 15223-1:2016
EN ISO 10993-1:2009/AC:2010	EN ISO 10993-5:2009	ISO 10993-10:2010	EN 1041:2008

Place, Date of Issue:

Foshan, 2nd April, 2020

Signature: Management Representative

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00301436

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/CA76**		
	Bezeichnung / Name **Landesamt für Arbeitsschutz, Verbraucherschutz und Gesundheit, Abteilung Gesundheit, Dezernat G4**		
	Staat / State **Deutschland**		Land / Federal state **Brandenburg**
	Ort / City **Zossen**		Postleitzahl / Postal code **15806**
	Straße, Haus-Nr. / Street, house no. **Wünsdorfer Platz 3**		
	Telefon / Phone **+49-331-8683852**		Telefax / Fax **+49-331-8683865**
	E-Mail / E-mail **medizinprodukte@lavg.brandenburg.de**		

Anzeige / Notification

	Registrierdatum bei der zuständigen Behörde Registration date at competent authority		Registriernummer / Registration number
	Typ der Anzeige / Notification type ☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change ☐ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer 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 ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ 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 ☐ 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 ☐ 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/0000047267**	
Bezeichnung / Name ***Osmunda Medical Technology Service GmbH***	
Staat / State **Deutschland**	Land / Federal state **Brandenburg**
Ort / City **Potsdam**	Postleitzahl / Postal code **14476**
Straße, Haus-Nr. / Street, house no. **Von Oppen-Weg, 15**	
Telefon / Phone **030 50590627**	Telefax / Fax
E-Mail / E-mail **eu@osmundacn.com**	

Hersteller / Manufacturer

Bezeichnung / Name **Foshan Kangfu Medical- Facility Factory**	
Staat / State **CN**	
Ort / City **Foshan, Guangdong**	Postleitzahl / Postal code **528531**
Straße, Haus-Nr. / Street, house no. **Gaofu 1st Road, Fuwan Town, Hecheng Street, Gaoming District**	
Telefon / Phone **0086 -0757-86430687**	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 **Min Yang**	
Staat / State **Deutschland**	Land / Federal state **Berlin**
Ort / City **Berlin**	Postleitzahl / Postal code **10787**
Straße, Haus-Nr. / Street, house no. **Keithstr. 2-4**	
Telefon / Phone **030 5059 0627**	Telefax / Fax
E-Mail / E-mail **min.yang@osmundacn.com**	

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	☐ Erstanzeige / Initial notification ☒ Änderungsanzeige / Notification of change		

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)

Klasse / Class

☒ I

☐ I - steril / sterile

☐ I - mit Messfunktion / with measuring function

☐ I - steril und mit Messfunktion / sterile and with measuring function

☐ IIa

☐ IIb

☐ III

☐ 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

☐ Aktives implantierbares Medizinprodukt / Active implantable medical device

☐ 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)	☐ ja / yes ☒ nein / no
Nummer(n) der Bescheinigung(en) / Certificate number(s)	
Handelsname des Produktes / Trade name of the device **Surgical medical mask**	
Produktbezeichnung / Name of device	
Nomenklaturcode / Nomenclature code **12-458**	
Nomenklaturbezeichnung / Nomenclature term **Maske, Chirurgie**	
Kategoriecode / Category code **10**	
Kategorie / Category **Produkte zum Einmalgebrauch**	
Kurzbeschreibung deutsch / German short description	
Kurzbeschreibung englisch / English short description **The surgical medical mask is applicable to the basic protection of medical personnel or related personnel, as well as the protection against the spread of blood, body fluids and splashes in the process of invasive operation.**	

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)

☐ Semikritische Medizinprodukte / Semicritical medical devices
- ☐ Gruppe A / Group A
- ☐ Gruppe B / Group B

☐ Kritische Medizinprodukte / Critical medical devices
- ☐ Gruppe A / Group A
- ☐ Gruppe B / Group B
- ☐ Gruppe C / Group C

Nummer der Bescheinigung / Certificate number

Sterilisationsverfahren / Sterilisation procedures
- ☐ Dampfsterilisation / Steam sterilisation
- ☐ Gassterilisation / Gas sterilisation
- ☐ Strahlensterilisation / Radiation sterilisation
- ☐ 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: Berlin

Datum / Date: 2020-04-05

OSMUNDA
Osmunda Medical Technology Service GmbH
Handelregister-Nr.: HRB 28353 P
Min Yang www.osmundacn.com

Name

Unterschrift / Signature

Bearbeitungsvermerke / Processing notes
Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority

Bearbeiter / Person responsible	Telefon / Phone

Foshan Kangfu Medical- Facility Factory

COA

No: 20200418-1 Test Number: 20200112

Sample Name:	Surgical medical mask	Number of sample:	60
Production unit:	Foshan Kangfu Medical- Facility Factory	Sample Character:	Soli
Trademark:	KangDeFu KindFul	Disinfection date	2020/4/12
Inspection date:	2020-4-13	Sample Receiving Date	2020-4-13
Inspection department:	laboratory		

Test results:

Test items	Test results	Reference Standards
Bacterial filtration efficiency (BFE),%	98.30%	≥ 98
Differentialpressure(Pa/cm2)	48.2	< 60
Splash resistancepressure (kPa)	16	≥ 16.0
Microbial cleanliness(cfu/g)	20	≤ 30

佛山市康复医疗器械厂 COA 质检专用章

Examiner: Linghua Guan Reviewer: Jun Yang Issuer: XianZhi Huang

April 18, 2020 April 18, 2020 April 18, 2020

Remark: 1. The COA will be invalid when it is altered, added and deleted, partially copied and not stamped the COA seal.

2. The COA shall not be used for commercial advertising.

3. The COA is in duplicate, one for the supplier, the other is deposited in the laboratory.

康福福 Kindful®

Certificate of conformity

Product name: Surgical Medical Mask

Model: Ear hanging type

Specifications: (18±1)cm × (9.5±0.5)cm

Quantity: 10 pcs/pack

Production batch number: 20200412

Production date: April 12,2020

Expiration date: April 11,2022

Inspector: Inspection 01

qualified

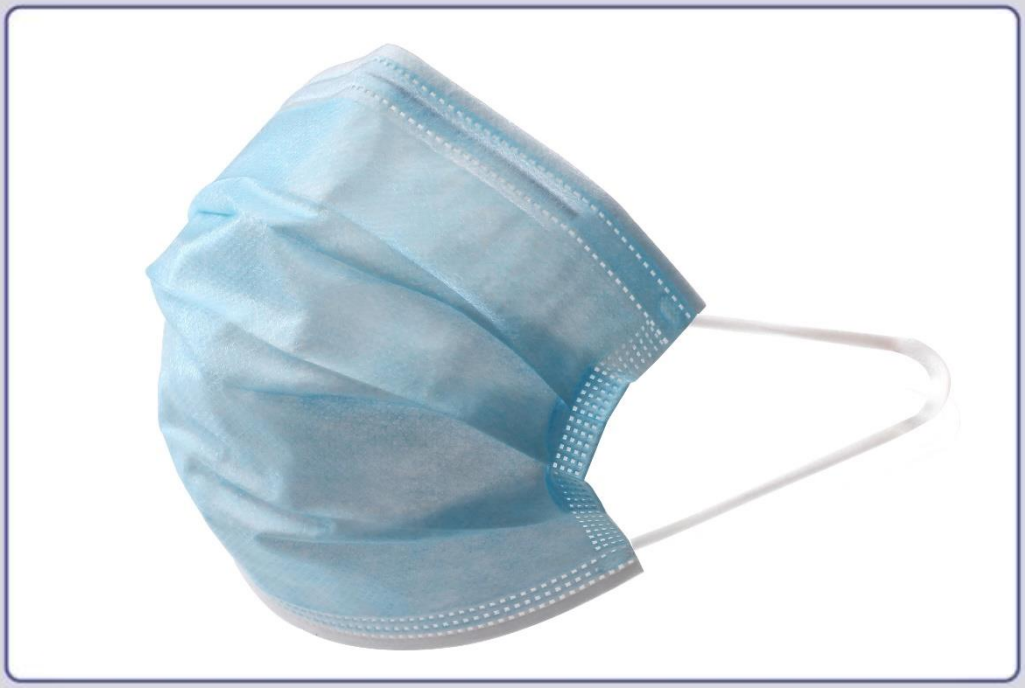
Executive standard: EN 14683-2019+AC:2019

Foshan Kangfu Medical - Facility Factory

KangDeFu Kindful

Disposable Protect ive Mask

Three layers with breathable comfort



50 pcs/box

Breathe Comfortably

Professional Protection

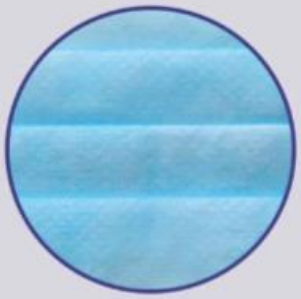
Safe and Healthy

Three Layers

LOWER AIR RESISTANCE, EASIER BREATHING

Powerful Barriers
Easy and Free Breathing

Filtering out 99.99% of bacteria, dust and particles

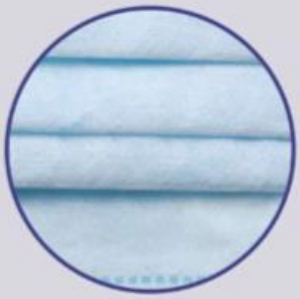


WATERPROOF NON-WOVEN FABRIC

BLOCKING INFILTRATION OF MIST AND WATER VAPOR

MEDICAL GRADE MELTBLOWN FABRIC

BLOCKING FINE DUST AND PARTICLES

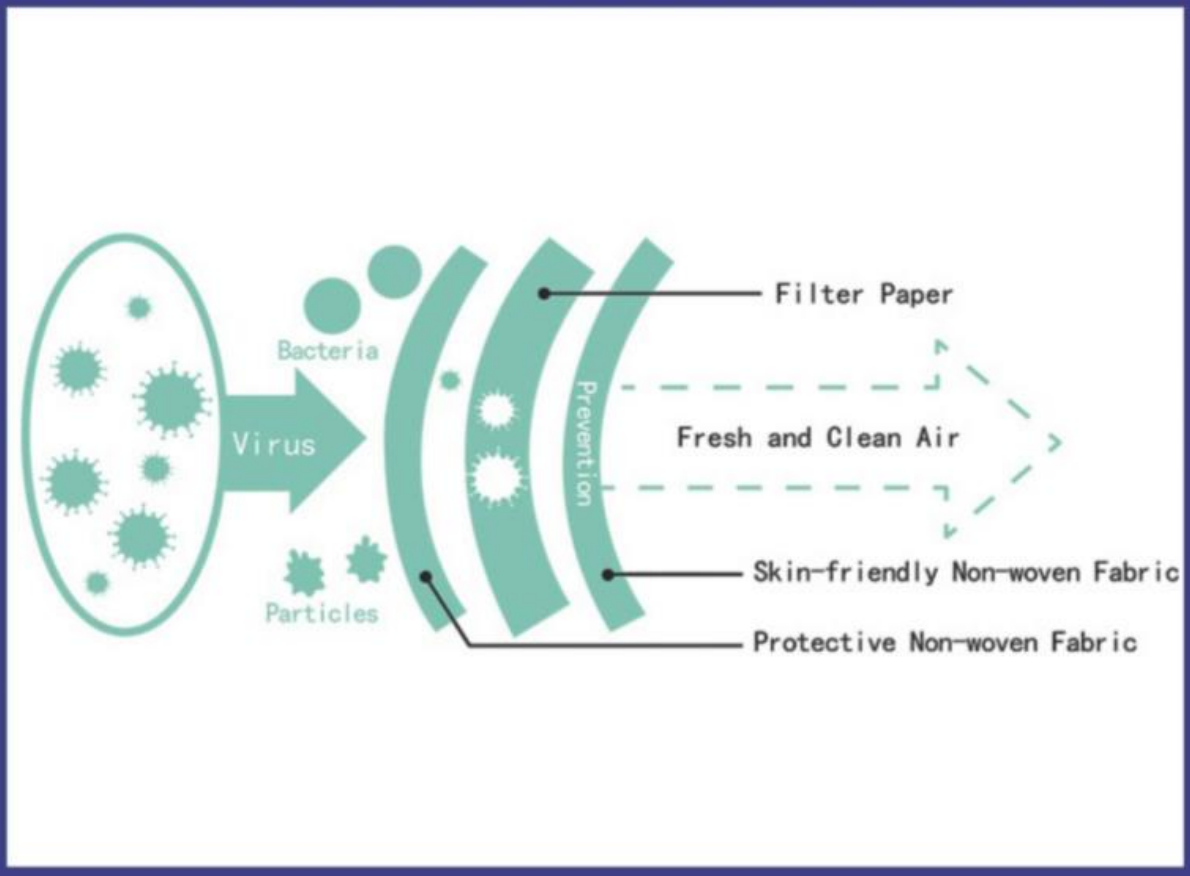


SKIN-FRIENDLY NON-WOVEN FABRIC

SKIN FRIENDLY COMFORTABLE SWEAT AND OIL-ABSORBING

KangDeFu Kindful

Three-layer High-tech Protection



KangDeFu Kindful

Fitting facial contours

Top Face fitting system

Three-dimensional cutting, Three-dimensional shape, more comfortable to wear

Face Fitting Design

Popular mask design, suitable for most people

Memory Nose Wire

Nose wires are made of memory metal to effectively fix the mask

Comfortable Ear-loops

Uniquely customized ear-loops prevent any harms to your ears

Product Specs

PRODUCT:	WENXIANG I-CLEAR
FEATURES:	DISPOSABLE PROTECTIVE MASK (3 LAYERS)
STANDARD	Q/XHB001-2020
PROTECTION:	LEVEL A
QUANTITY	50PCS / BOX
SPECIFICATIONS	18.0 X 9.5 cm 3 LAYERS

KangDeFu Kindful


SURGICAL MEDICAL MASK
Ear hanging type
10PCS


KangDeFu Kindful
SURGICAL MEDICAL MASK
Ear hanging type
EN 14683 TYPE IIR
Bacterial filtration efficiency (BFE), ≥98%
Manufacturer Name:Foshan Kangfu Medical- Facility Factory
Manufacturer Address:Gaofu 1st Road, Fuwan Town, Hecheng Street, Gaoming District,
Foshan City, Guangdong Province, 528531,China
Tel:+86 757-86430687
EC REP
Osmunda Medical Technology Service GmbH Von Oppen-Weg 15, 14476 Potsdam, Germany
Tel: +49 30 5059 0627
Email: eu@osmundacn.com
DIMDI code: DE/0000047267


KangDeFu Kindful
CE
SURGICAL MEDICAL MASK
Ear hanging type
MEAS ∴ 645*490*400MM

统一社会信用代码

91440608193550251 9

营业执照

(副 本)(副本号:2-1)

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　佛山市康复医疗设备厂

类　　型　集体所有制

法定代表人　黄伟民

经营范围　生产、销售：III类6864医用卫生材料及敷料，II类6866医用高分子材料及制品（凭有效许可证经营）。制造、加工、修理：轮椅、拐杖、残疾人机动车；加工：塑料，纺织品；货物或技术进出口（国家禁止或涉及行政审批的货物和技术进出口除外）。加工：塑料，纺织品。〓（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。）〓

注册资金　人民币伍拾万元

成立日期　1995年05月30日

经营期限　长期

住　　所　佛山市高明区荷城街道富湾高富一路

登记机关　佛山市高明区市场监督管理局

2020 年 3 月 18 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年度报告

国家市场监督管理总局监制

医疗器械生产许可证

许可证编号：粤食药监械生产许20010139号

企业名称：佛山市康复医疗设备厂

生产地址：佛山市高明区荷城街道富湾高富一路

法定代表人：黄伟民

生产范围：见医疗器械生产产品登记表

企业负责人：黄伟民

住　　所：佛山市高明区荷城街道富湾高富一路

发证部门：广东省食品药品监督管理局

有效期限：至 2020 年 11 月 15 日

发证日期：2016 年 12 月 01 日

国家食品药品监督管理总局制

医疗器械生产产品登记表

企业名称	佛山市康复医疗设备厂
许可证编号	粤食药监械生产许20010139号
许可证有效期限	至2020年11月15日
生产范围	Ⅱ类6864医用卫生材料及敷料，Ⅱ类6866医用高分子材料及制品

生产产品列表

序号	产品名称	注册号	登载日期	备注
1	外科纱布敷料	粤械注准20152640596	2015年11月16日	
2	一次性使用医用口罩	粤械注准20152641443	2016年06月06日	
3	一次性使用手术衣	粤械注准20172641690	2018年08月08日	
4	一次性使用无菌导尿包	粤械注准20172661795	2018年08月08日	
5	医用外科口罩	粤械注准20172641484	2018年08月08日	

发证部门（公章）：

2018年08月08日

对外贸易经营者备案登记表

统一社会信用代码：91440608193550251 9

备案登记表编号：02477932　　进出口企业代码：————————

经营者中文名称	佛山市康复医疗设备厂		
经营者英文名称	Foshan Kangfu Medical- Facility Factory		
组织机构代码	————	经营者类型（由备案登记机关填写）	集体企业
住　所	广东省佛山市高明区荷城街道富湾镇高富一路		
经营场所（中文）	广东省佛山市高明区荷城街道富湾镇高富一路		
经营场所（英文）	Gaofu 1st Road, Fuwan Town, Hecheng Street, Gaoming District, Foshan City, Guangdong Province		
联系电话	0757-88818892	联系传真	0757-88819028
邮政编码	528500	电子邮箱	3475923568@qq.com
工商登记注册日期	1995-5-30	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	黄伟民	有效证件号	440601196510050613
注册资金	伍拾万元	（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	

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

2020 年 03 月 19 日

中华人民共和国医疗器械注册证

注册证编号：粤械注准 20172641484

注册人名称	佛山市康复医疗设备厂
注册人住所	佛山市高明区荷城街道富湾高富一路
生产地址	佛山市高明区荷城街道富湾高富一路
产品名称	医用外科口罩
型号、规格	型号：挂耳式、绑带式；规格：（18±1）cm×（9.5±0.5）cm
结构及组成	由罩体、口罩带、鼻夹组成。
适用范围	适用于医务人员或相关人员的基本防护，以及在有创操作过程中阻止血液、体液和飞溅物传播的防护。
附　　件	产品技术要求。
其他内容	无
备　　注	原产品注册证号：粤食药监械（准）字 2014 第 2640314 号

审批部门：广东省食品药品监督管理局　　批准日期：2017 年 08 月 23 日

有效期至：2022 年 08 月 22 日

医疗器械注册专用章

European Commission

Declaration of Conformity

Manufacturer: Foshan Kangfu Medical- Facility Factory

Address: Gaofu 1st Road, Fuwan Town, Hecheng Street, Gaoming District, Foshan City, Guangdong Province, 528531, China

EU Authorised Representative:

Osmunda Medical Technology Service GmbH

Address: Von Oppen-Weg 15, 14476 Potsdam, Germany

DIMDI code: DE/0000047267

Device: Surgical medical mask **Model**: Ear hanging type

Classification (MDR, Annex VIII): Class I

Conformity assessment route: ANNEX II+ANNEX III

We herewith declare that the above mentioned product meet the provisions of the following regulation (EU) MDR 2017/745. All supporting documentations are retained under the premises of the manufacturer.

CE

General applicable regulation:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

Standard Applied:

EN ISO 13485:2016	EN ISO 14971:2012	EN 14683:2019 +AC: 2019	BS EN ISO 15223-1:2016
EN ISO 10993-1:2009/AC:2010	EN ISO 10993-5:2009	ISO 10993-10:2010	EN 1041:2008

Place, Date of Issue:

Foshan, 2nd April 2020

Signature:

Jianzhi Huang

Management Representative

HOW TO PROPERLY WEAR

① Open the mask and keep the skin dry with the white side facing inward and nose wire uppermost.

② Position the ear loops around both ears and even the stress.

③ Open the mask and keep the skin dry with the white side facing inward and nose wire uppermost.

Precaution

1. Do not use if the product is presenting bad odor, bleached color or mold.

2 This product is not suitable for protection against toxic gases and severe pollution.

3 Any use discomfort, requires the to replace his mask with a new one.. This mask is of one-time use. Cleaning is not enough a measure to prevent the spreading of diseases.

Storage

It needs to be stored in a dry and clean place. It is prohibited by law to mix and store with toxic, harmful and polluting materials

KangDeFu Kindful

SUBJECT Physical & Microbiological 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 Foshan Kangfu Medical- Facility Factory

CLIENT ADDRESS He Cheng Jie Dao Fu Wan Zhen Gao Fu Yi Lu, Gaoming District, Foshan City, Guangdong Province, China

TEST PERIOD 11-Apr-2020~19-Apr-2020

Prepared By

Bella Xu
(Bella Xu)
Report Drafter

Authorized By

Leo Liu
(Leo Liu)
Authorized Signatory

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.

TEST REPORT

Sample Description	:	surgical face mask
Sample Quantity	:	60 pieces
Lot Number/Batch Code	:	200401
Specification	:	Hanging ear type
Size	:	/
Type of Mask	:	Type IIR
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
# = No comment;
N.D. = Not detected.

Photo of Samples

Chemical/Microbiology Laboratory:
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Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
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No.151 Heng Tong Road Shanghai
200 070 P.R.China

Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.5% Specimen 2#: 99.5% Specimen 3#: 99.5% Specimen 4#: 99.5% Specimen 5#: 99.6%
2	Differential Pressure Test	42.9 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~13#: None seen
4	Microbial Cleanliness Test	Specimen 1#: <1 CFU/g Specimen 2#: <1 CFU/g Specimen 3#: <1 CFU/g Specimen 4#: <1 CFU/g Specimen 5#: <1 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

2. Sample description was given by client

Sample description : surgical face mask
Specification : Hanging ear type
Lot Number : 200401
Sample Receiving Date : 2020-04-11

3. Test Method

EN 14683:2019+AC:2019(E) Annex B

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538.
4.2 Peptone water.
4.3 Tryptic Soy Broth(TSB).
4.4 Tryptic Soy Agar(TSA).
4.5 Bacterial filtration efficiency test apparatus.
4.6 Six-stage viable particle Anderson sampler.
4.7 Flow meters.

5. Test specimen

5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

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6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
   6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
   6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
   6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
   6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: $77cm^2$).
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (37±2)°C for (20 to 52) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE=(C-T)\,/\,C\times 100$$

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.

8. Test results*

Stage Number \ *P* Value	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	36	48	0	0	0	0	0	0
2	60	70	0	0	0	0	0	0
3	183	328	0	0	0	0	0	0
4	508	610	0	1	6	0	0	0
5	883	793	0	6	5	11	5	8
6	606	703	0	5	1	2	7	2
Total (*T*), CFU	2276	2552	<1	12	1	13	12	10
Average (C), CFU	$2.4 \times 10^3 = (P_A+P_B) / 2$							
BFE ,%				99.5	99.5	99.5	99.5	99.6
Requirements	≥ 98							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

Chemical/Microbiology Laboratory:
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TÜV®

Differential pressure Test

1.Purpose

The purpose of the test was to measure the differential pressure of masks.

2.Sample description was given by client

Sample description : surgical face mask
Specification : Hanging ear type
Lot Number : 200401
Sample Receiving Date : 2020-04-11

3.Test Method

EN 14683:2019+AC:2019(E) Annex C

4. Apparatus and materials

Differential pressure testing instrument

5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5) °C and (85±5)% relative humidity.

6. Procedure

6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.
6.2 The pretreated specimen is placed across the orifice (total area 4.9cm^2, test area diameter 25mm) and clamped into place so as to minimize air leaks.
6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.
6.4 The differential pressure is read directly.
6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (Pa/cm^2)	Average (Pa/cm^2)	Requirements	Judgement
1#	48.0	42.9	< 60	Pass
2#	46.3			
3#	41.8			
4#	39.4			
5#	39.1			

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200 070 P.R.China

Synthetic Blood Penetration Test

1.Purpose

For evaluation of resistance of masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by client

Sample description	:	surgical face mask
Specification	:	Hanging ear type
Lot Number	:	200401
Sample Receiving Date	:	2020-04-11

3.Test Method

ISO 22609:2004

4.Apparatus and materials

4.1 Synthetic blood.

4.2 Tensiometer.

4.3 Synthetic blood penetration test apparatus;

4.4 Targeting plate.

4.5 Air pressure source.

4.6 Ruler.

4.7 Balance.

4.8 Controlled temperature and humidity chamber.

5.Test specimen

5.1 As requested by client, take a total of 13 test specimens.

5.2 Prior to testing, condition all test specimens for a minimum of 4h at (21±5)°C and (85±5) % relative humidity.

6.Procedure

6.1 Prepare the synthetic blood (40~44 mN/m) for the test.

6.2 Determine the density of the synthetic blood.

6.3 Fill the reservoir with new synthetic blood.

6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.

6.5 Set the reservoir pressure to the approximate pressure.

6.6 Place the targeting plate approximately 1 cm away from the mask.

6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

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6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.003, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1s difference in spurt duration (g)		
	Min.	Target	Max.
120	3.002	3.063	3.124

6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.

6.11 Record the weight difference for the spurts exiting the nozzle.

6.12 Record the pressure in the reservoir.

6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 % ~ -5 % of the difference in weight from the nozzle.

6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.

6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).

6.18 For standard synthetic blood, the timer duration can be estimated using the formula: (p is the density of the test fluid.) $t = 0.5 + (2\times p$ - g at 0.5 s) / (g at 1.5 s - g at 0.5 s).

6.19 Record the timer setting to use as the starting point for subsequent testing.

6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.

6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.

6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.

6.23 Report the results (none / penetration) for each test specimen at the test pressure.

Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
11#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass

Microbial Cleanliness Test

1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

2. Sample description was given by client

Sample description	:	surgical face mask
Specification	:	Hanging ear type
Lot Number	:	200401
Sample Receiving Date	:	2020-04-11

3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

4. Apparatus and materials

4.1 Orbital shaker.
4.2 0.45 um filter.
4.3 Tryptic Soy Agar (TSA).
4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
4.6 Extraction apparatus.

5. Test specimen

5.1 As requested by client, take a total of 5 mask samples.
5.2 Mask samples for testing are provided in the original primary packaging.
5.3 Condition at (18 to 26)℃ and (45 to 65)% relative humidity during testing.

6. Procedure

6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA for fungi enumeration.
6.5 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.
6.6 Calculate the colonies of each agar plate.

7. Calculation

For each test specimen calculate the microbial cleanliness as follows by counting the total colonies of the TSA and SDA plates.

Chemical/Microbiology Laboratory:
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Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	0	0	<1	According to EN ISO 11737-1:2018 the microbial cleanliness of the mask shall be ≤30 CFU/g tested.	Pass
2#	0	0	<1		
3#	0	0	<1		
4#	0	0	<1		
5#	0	0	<1		

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

Certificate of conformity

Product name: Surgical Medical Mask

Component content : Nonwoven fabric white 27.5% meltblown fabric 23%, nonwoven fabric blue 27.5%, aluminum strip 7.7%, ear strap 14.3

Model: Ear hanging type

Quantity: 10 pcs/pack

Production batch number: 20200412

Production date: April 12, 2020

Expiration date: April 11, 2022

Inspector: Inspection qualified 01

Executive standard: EN 14683-2019+AC: 2019

Foshan Kangfu Medical - Facility Factory

Certificate of conformity

Product name: Surgical Medical Mask

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Model: Ear hanging type

Quantity: 10 pcs/pack

Production batch number: 20200412

Production date: April 12, 2020

Expiration date: April 11, 2022

Inspector: Inspection qualified 01

Executive standard: EN 14683-2019+AC: 2019

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