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Henan Yubei Sanitary Materials Co.,Ltd

Company Introduction and product presentation

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COMPANY INTRODUCTION

Henan Yubei Sanitary Materials Co., Ltd was established in May 1998.It is a professional manufacturer of medical devices and sanitary materials.

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The company's leading products: disposable medical masks, caps, surgical gowns, medical gauze, dressing bags, surgical bags, surgical masks, medical cotton swabs, iodine cotton swabs, disposable medical pads, disposable sterile catheters, etc. medical products.

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WORKSHOP AND TESTING CENTER

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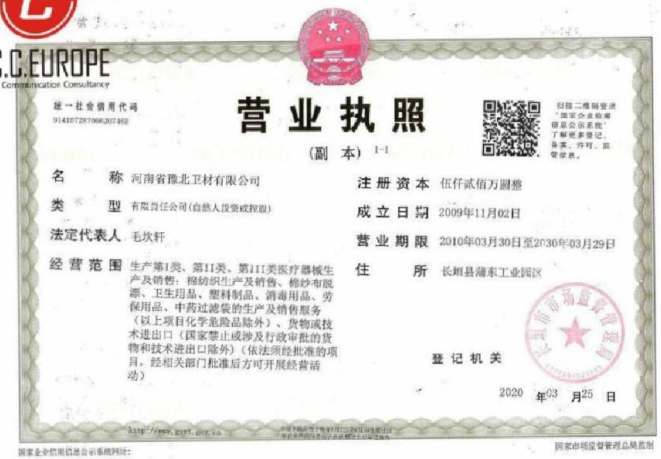
China business execution and medical device license



营业执照

（副本）1-1

名　　称　河南省豫北卫材有限公司
类　　型　有限责任公司（自然人投资或控股）
法定代表人　毛坎轩
经营范围　生产第I类、第II类、第III类医疗器械生产及销售；棉纺织生产及销售、棉纱布脱脂、卫生用品、塑料制品、消毒用品、劳保用品、中药过滤袋的生产及销售服务（以上项目化学危险品除外）、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）（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）
注册资本　伍仟贰佰万圆整
成立日期　2009年11月02日
营业期限　2010年03月30日至2030年03月29日
住　　所　长垣县蒲东工业园区
登记机关　2020年03月25日

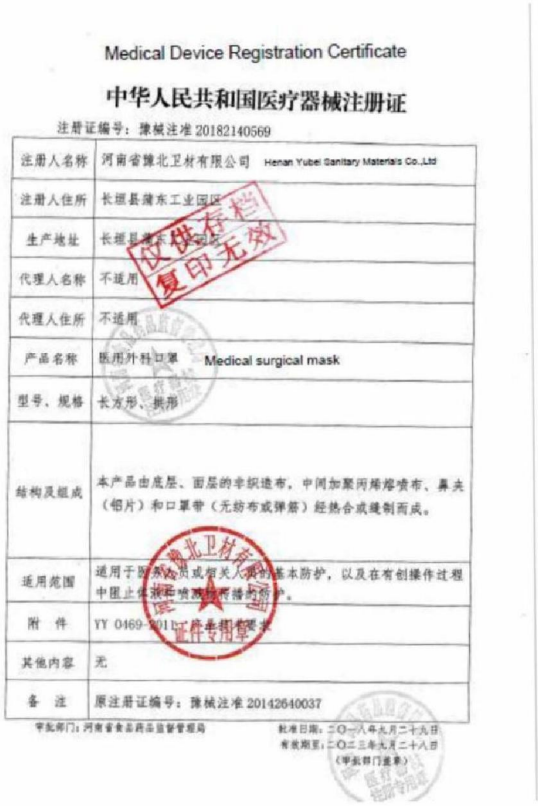
医疗器械生产许可证

Medical Device Production License

许可证编号：豫食药监械生产许20150112号

企业名称：河南省豫北卫材有限公司
法定代表人：毛坎轩
企业负责人：毛坎轩
住　　所：长垣县蒲东工业园区
生产地址：长垣县蒲东工业园区
生产范围：
发证部门：河南省药品监督管理局
有效期限：至 2020 年 08 月 27 日
发证日期：2019 年 10 月 08 日

仅供存档 复印无效



Medical Device Registration Certificate

中华人民共和国医疗器械注册证

注册证编号：豫械注准 20182140569

注册人名称	河南省豫北卫材有限公司 Henan Yubei Sanitary Materials Co.,Ltd
注册人住所	长垣县蒲东工业园区
生产地址	长垣县蒲东工业园区
代理人名称	不适用
代理人住所	不适用
产品名称	医用外科口罩 Medical surgical mask
型号、规格	长方形、拱形
结构及组成	本产品由底层、面层的非织造布，中间加聚丙烯熔喷布、鼻夹（铝片）和口罩带（无纺布或弹筋）经热合或缝制而成。
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体液飞溅污染佩戴者的防护。
附　件	YY 0469-2011《医用外科口罩》
其他内容	无
备　注	原注册证编号：豫械注准 20142640037

审批部门：河南省食品药品监督管理局　批准日期：二〇一八年九月二十九日　有效期至：二〇二三年九月二十八日

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China Inspection Certification

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Test Report

检 验 报 告

报告编号

委 托 方

样品名称

型 号

检验类别

国家食品药品监

国家食品药品监督管理局上海医疗器械质量监督检验中心

检 验 报 告 首 页

国家食品药品监督管理局上海医疗器械质量监督检验中心

检 验 报 告

国家食品药品监督管理局上海医疗器械质量监督检验中心

检 验 报 告 照 片 页

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CE certification

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

Sungo
global service

CERTIFICATE OF NOTIFICATION

This is to certify that, according to the council directive 93/42/EEC, SUNGO performed all notification duties and responsibilities as the European authorized representative of:

Applicant: Henan Yubei Sanitary Materials Co., Ltd
Address: Pudong Industrial Park, Changyuan County, Henan Province, China

The Manufacturer has provided SUNGO with all the appropriate declarations according to the 93/42/EEC Directive requirements including the EC Declaration of Conformity confirming that his medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 93/42/EEC.

Product(s): Masks, Protective Clothing, Isolation gown
Type(s): Masks: Large Size、Small Size
Protective Clothing: Type I、Type II
Isolation gown: Type A、Type B、Type C
Product Classification: Class I

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

The notification of aforementioned device has been completed by the European Representative in Netherlands. The Netherlands Competent Authority is notified of the manufacturer's medical devices and has allocated registration. NOTIS number is CIBG-20200617.

Executive Director
Sungo
CERTIFIED

Issued: Mar. 23 2020
Cert. No.: EU211518
Expiration Date: Mar. 22 2025

CE
This is not a CE mark and is only provided as a template for informational purpose.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

Sungo
global service

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SUNGO Europe B.V. documents

CIBG
Ministerie v
Website en Sp

> Kanoniersboo Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer Luo
Olympisch Stadion 24
1076 DE Amsterdam

Datum: 19 maart 2020
Betreft: aanmelding medische hulpmiddelen klasse I

Geachte heer Luo,

Graag bevestig ik hierbij de ontvangst op 14 maart 2020 van d
artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bed
Sanitary Materials Co., Ltd. met Europees gemachtigde SUN
onderstaande medische hulpmiddelen, ingedeeld in risicoklass
producten zijn onder volgend kenmerk geregistreerd. Ik verzo
verdere correspondentie betreffende een of meer van deze
bijbehorende kenmerk te vermelden.

Face Mask
(geen merknaam) (NL-CA002-2020-49609)
Isolation gown
(geen merknaam) (NL-CA002-2020-49611)
Protective Clothing
(geen merknaam) (NL-CA002-2020-49610)

Toekomstige wijzigingen in bovengenoemde gegevens –
eventuele wijziging van de indeling in risicoklasse in verband met
Europese regelgeving inzake de classificatie van medische hulpm
voortschrijdend wetenschappelijk inzicht (zie art.9, lid 3 van E
93/42/EEG) – dient u te zijner tijd mede te delen.

Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededo
is een medisch hulpmiddel ter aflevering voorhanden te hebbe
leveren indien niet aan de voor dat medisch hulpmiddel geldend
bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wo
name wijzen wij u op de Nederlandse-taaleis, de eisen voor het
houden van de technische documentatie en de plicht tot het hebb
Market Surveillance- en vigilantiesysteem.

Tevens wijs ik u er voor de goede orde
mededeling betreffende de aflevering van de
een administratieve handeling betreft. Deze o
geen besluit betreffende de kwalificatie van
medisch hulpmiddel in de zin van art. 1 WM
risicoklasse I.

Let op: de notificatie van uw MDD klasse I pro
Valt uw MDD klasse I (laag risico) product ond
2017/745 (MDR) onder een hogere risicoklasse
uiterlijk 25 mei 2024 op de markt blijven als M

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dhr. M.J. van de Velde

Dhr. M.J. van de Velde

Ref. No.:

MD

Party A甲方:
Add地址:
Contact联系人:
Tel电话: +86 0373-8848993
Fax传真: +86 0373-8816228
Email邮箱:

Party B乙方: *SUNGO Europe B*
VAT: NL857821659B01
Add地址: Olympisch Stadion 2
Contact联系人: SUNGO Secret
Tel电话/Fax传真: +31 (0) 2021
E-mail邮箱: ec.rep@sungogrou

Party A hereby appoints Party B as th
CE mark and Party B accepts the ap
in the market of European Union (EU
甲方任命乙方为CE医疗产品欧盟授权
权代表，双方签署下列协议：

1. Party A 甲方

1.1 Party A assures to provide the up
to Party B (Product categories re
not provide the required techni
certification or before using CE
terminated automatically, Party A
should be the electronic copy (
submitted if required by the com
files in appendix B.
甲方确保在认证结束后向乙方提供
证的产品信息见附录一），如果甲
使用CE标记之前，仍然没有提供
此协议而引起的所有后果，甲方必
任何一种提交，书面文件只有在
见本协议"附件 ..."。

1.2 Party A shall keep the Party I
information in attachment 1 at all
如果附件1中的文件有任何变化应

1.3 If any accident/near accident of
investigation in premarket stage,

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SUNGO/ECR/NED/MDR/01 V2.0

1) The day upon Part A's CE Certificate be withdrawn temporarily, be closed or be recalled by the notified body.
甲方的CE证书因被被发证机构暂时吊销/关闭/收回之日；

2) 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" products. 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。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。

3) Party A doesn't payoff the service fee according to this agreement and refuse to explain on the deadline.
甲方没有按协议规定的最后期限内付清欧盟代表服务费/拒绝不作解释的。

Company A: 2020.3.11
Date
Signature

Company B: 2020.3.11
Date
Signature

SUNGO EUROPE B.V. COMMON SEAL

6 / 11

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German TUV TYPE II R test report

Produkte
Products

TÜVRheinland®

Prüfbericht-Nr.: *Test Report No.:*	50362818 001	**Auftrags-Nr.** *Order No.:*	168258394	Seite 1 von 12 *Page 1 of 12*
Kunden-Referenz-Nr.: *Client Reference No.:*	N/A	**Auftragsdatum:** *Order date:*	Mar. 30, 2020	
Auftraggeber: *Client:*	Henan Yubei Sanitary Materials Co., Ltd. Pudong Industrial Park, Changyuan County, Changyuan, 453400, P.R.China			
Prüfgegenstand: *Test item:*	Face Mask			
Bezeichnung / Typ-Nr.: *Identification / Type No.:*	Rectangle, Type IIR			
Auftrags-Inhalt: *Order content:*	Type test			
Prüfgrundlage: *Test specification:*	EN 14683:2019+AC:2019 except for clause 5.2.6			

Wareneingangsdatum: *Date of receipt:*	Apr. 01, 2020	See Attachment: Photo documentation for details.
Prüfmuster-Nr.: *Test sample No.:*	04200208	
Prüfzeitraum: *Testing period:*	Apr. 02, 2020 to Apr. 24, 2020	
Ort der Prüfung: *Place of testing:*	See page 3	
Prüflaboratorium: *Testing laboratory:*	TÜV Rheinland (Shenzhen) Co., Ltd.	
Prüfergebnis*: *Test result*:*	Pass	

geprüft von / *tested by:*	**kontrolliert von** / *reviewed by:*
Amanda Liu	Angela Ch
Apr. 24, 2020 Amanda Liu/Project Engineer	Apr. 26, 2020 Angela Chen / Department Manager
Datum Name / Stellung Unterschrift	Datum Name / Stellung Unterschrift

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EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No. ..... :	50362818 001
Date of issue ..... :	See cover page
Total number of pages ..... :	See cover page
Testing Laboratory ..... :	**TÜV Rheinland (Shenzhen) Co., Ltd.**
Address ..... :	1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Applicant's name ..... :	Henan Yubei Sanitary Materials Co., Ltd.
Address ..... :	Pudong Industrial Park, Changyuan County, Changyuan, 453400, P.R.China
Test specification:	
Standard ..... :	EN 14683:2019+AC:2019
Test procedure ..... :	Type test
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	EN 14683:2019+AC:2019_A
Test Report Form Originator ..... :	TÜV Rh (SZ)
Master TRF ..... :	2020-03
Test item description ..... :	Face Mask
Trade Mark ..... :	豫北 YU BEI
Manufacturer ..... :	Same as the applicant
Model/Type reference ..... :	Rectangle, Type IIR
Classification ..... :	Type IIR

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EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
4	**Classification**		P
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.	Type IIR	P
5	**Requirements**		P
5.1	**General**		P
5.1.1	**Materials and construction**		P
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	3 ply designed with two layers of polypropylene spunbond nonwoven and one layer of polypropylene melt-blown nonwoven.	P
	The medical face mask shall not disintegrate, split or tear during intended use.		P
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.		P
5.1.2	**Design**		P
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.		P
	Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	With nose clip	P
5.2	**Performance requirements**		P
5.2.1	**General**		P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

5.2.2	TABLE: Bacterial filtration efficiency (BFE)							P
Batch/ lot no.:	Test Specimen no.:	Dimension of the test specimen L x W (mm x mm)	test area (cm^2)	Flow rate (l/min)	Mean of the total plate counts of the two positive controls	Mean plate count of the negative controls	BFE for each test specimen (%)	Remarks
04200208	1	158x154	63.6	28.3	1873	0	99.79	--
	2	157x152	63.6	28.3			99.57	--
	3	159x153	63.6	28.3			99.25	--
	4	158x154	63.6	28.3			99.73	--
	5	158x153	63.6	28.3			99.57	--

Supplementary information:
1, Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.
2, The side of the test specimen was facing towards the challenge aerosol: the outside of the test specimen.

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Bandage Surgical mask (TYPE II R)

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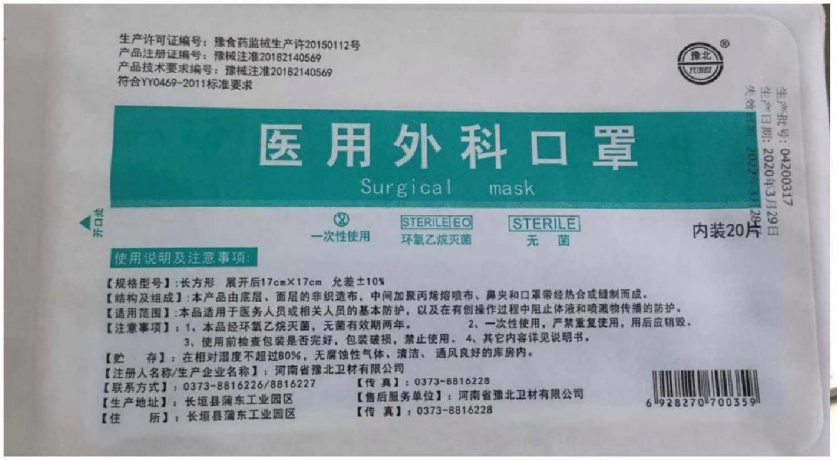
Packing box



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English label on the carton

Product Name	Surgical mask(TypeIIR)	Carton Size:	51*35*44cm
Qty in this carton	2000pcs	Packaging	20pcs-polybag
Gross Weight	8KGS	Net Weight:	7.7KGS
LOT	04200409	Brand	Yu Bei
Product Date	09-4-2020	expiry date	08-4-2022
Manufacturer	Henan Yubei Sanitary Materials Co.,Ltd.		

豫北 YUBEI ®

DISPOSABLE STERILE EO STERILE