Face Masks

Key Product Specs:

- FDA Registered
- BFE>=95

Product Display

Photo

Detail

Packing

Business & Medical Licenses

医疗器械生产许可证

许可证编号：鄂食药监械生产许 20160725 号

企业名称：仙桃市道琦塑业股份有限公司

生产地址：仙桃市彭场镇挖沟新区 83 号

法定代表人：别道奇

生产范围：
[illegible]医用卫生材料及敷料。***

企业负责人：别道奇

住　　所：仙桃市彭场镇挖沟新区 83 号

发证部门：湖北省食品药品监督管理局

有效期限：至 2021 年 10 月 31 日

发证日期：2017 年 06 月 17 日

国家食品药品监督管理总局制

营业执照

(副本)

(1-1)

统一社会信用代码 91429004181667161H

名　　称　仙桃市道琦塑业有限公司

类　　型　[illegible]公司(自然人投资或控股)

住　　所　仙桃[illegible]挖沟新区83号

法定代表人　别道奇

注册资本　伍佰万圆整

成立日期　2004年12月08日

营业期限　长期

经营范围　二类医疗器械：6864医用卫生材料及敷料；[illegible]品的生产、销售；功能性塑料制品、功能性非织造[illegible]发、生产、销售；非织造布制品智能机械、织造[illegible]智能织机、塑料制品智能机械、智能家电产品的研发、制造、销售；经营本企业生产自产产品及技术的出口业务；经营本企业生产、科研所需的原辅材料、机械设备、零配件及技术的进口业务（国家限定公司经营和国家禁止进出口的商品除外）；经营进料加工和"三来一补"业务；[illegible]及许可经营项目，应取得相关部门许可后方可经营）

登记机关　仙桃市工商行政管理局

2016 年 03 月 24 日

企业信用信息公示系统网址：

中华人民共和国国家工商行政管理总局监制

Company Info

Daoqi is located in No8 HeLi Road XianTao where is just in the west of WUHAN 80 kilometers, On the north of Han shui and South of the Yangtze river. It also enjoys Janghan plain of the good reputation :home of gymnastics. It is in 1988 that our company has been founded which is focused on developing new products and has got 8 national patents.

Test Report

intertek
Total Quality. Assured.

TEST REPORT

Number: GZHT02280165

Report Ref:	GZHT02280165
Date Received:	Apr 13, 2020
Date Issued:	Apr 23, 2020

Company Name:	XIANTAO DAOQI PLASTIC CO.,LTD
Address:	NO.83 WAGOU NEW DISTRICT PENGCHANG TOWN XIANTAO CITY, HUBEI PROVINCE CHINA
Contact Name:	Wendy Bie

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:	
End Uses	: Non-Sterile Medical Face Mask
Ratings	: Type I/Type IIR
Sample Name	: Disposable Medical Face Mask
Size	: 17.5cmx9.5cm
Colour	: Blue
Standard	: EN 14683:2019+AC:2019
Brand	: BIEDQ
Manufacturer	: Xiantao Daoqi Plastic Co., Ltd
Date received/ Test Started	: Apr 13, 2020
Ref	: Type: DQSM01 Product Registration Number: 鄂械注准 20162642299

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou GDD Branch

Lin Lin
General Manager

Can / pennytao

Page 1 Of 6

intertek
Total Quality. Assured.

TEST REPORT

Number: GZHT02280165

Original Sample Photo

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou GDD Branch

Lin Lin
General Manager

Can / pennytao

Page 2 Of 6

CE Notification

Sungo

CE Notification Confirmation

This is to confirm that, according to the council directive 93/42/EEC (MDD), SUNGO Europe B.V. performed the notification duties and responsibilities as the European authorized representative of:

Xiantao Daoqi Plastic Co., Ltd.
No.83 Wagou New District, Pengchang Town, Xiantao City, Hubei Province, China

The Manufacturer has provided SUNGO Europe B.V. with the EC Declaration of Conformity confirming that the medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 93/42/EEC.

According to 93/42/EEC (MDD), the European Databank on Medical Devices (EUDAMED) is established as of May 1 2011. The Netherlands Competent Authority is notified of the manufacturer's medical devices and has allocated registration number.

Face Mask
Class I according to Annex IX of 93/42/EEC
GMDN: 35177
CIBG Number: NL-CA002-2020-50528

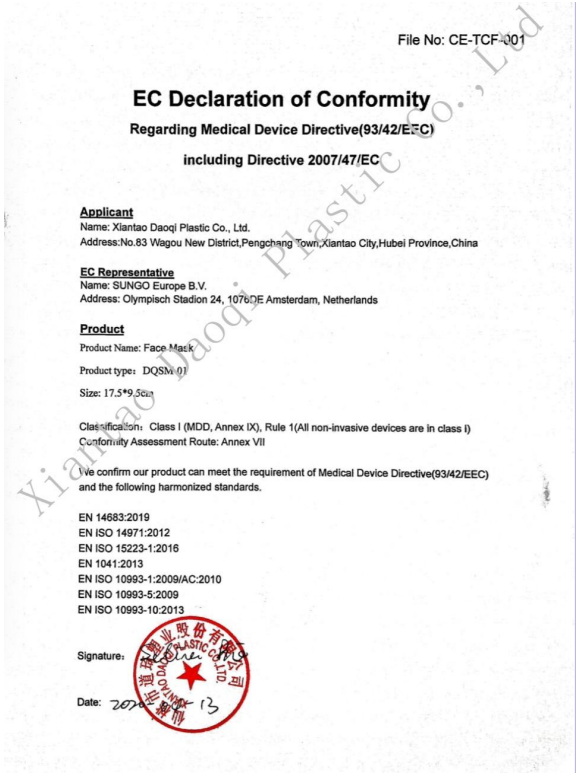
Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This document should be used together with the competence authority notification letter and the Declaration of Conformity issued by the Manufacturer. This document will become to be invalid once the notification status is changed or the EAR agreement is terminated.

Reference Number: EUCAN00205
Issue date: May.06, 2020

SUNGO Europe B.V.
Olympisch Stadion 24,1076DE
Amsterdam, Netherlands
ec.rep@sungogroup.com

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Authorized Signature
Only used for the EU Representative Signature



File No: CE-TCF-001

EC Declaration of Conformity

Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Applicant
Name: Xiantao Daoqi Plastic Co., Ltd.
Address:No.83 Wagou New District,Pengchang Town,Xiantao City,Hubei Province,China

EC Representative
Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product
Product Name: Face Mask
Product type：DQSM-01
Size: 17.5*9.5cm

Classification：Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)
Conformity Assessment Route: Annex VII

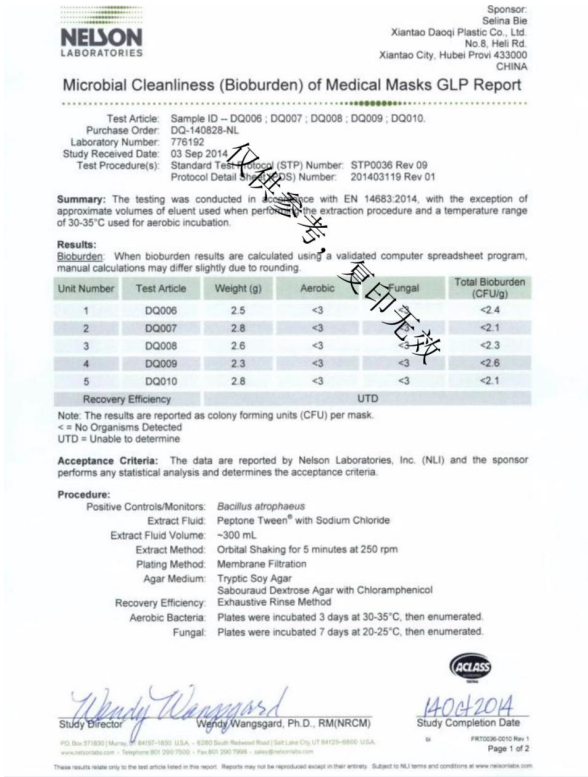
We confirm our product can meet the requirement of Medical Device Directive(93/42/EEC) and the following harmonized standards.

EN 14683:2019
EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2013
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013

Signature:

Date: 2020 13

Nelson Test Report



NELSON LABORATORIES

Sponsor:
Selina Bie
Xiantao Daoqi Plastic Co., Ltd.
No.8, Heli Rd.
Xiantao City, Hubei Provi 433000
CHINA

Microbial Cleanliness (Bioburden) of Medical Masks GLP Report

Test Article: Sample ID -- DQ006 ; DQ007 ; DQ008 ; DQ009 ; DQ010.
Purchase Order: DQ-140828-NL
Laboratory Number: 776192
Study Received Date: 03 Sep 2014
Test Procedure(s): Standard Test Protocol (STP) Number: STP0036 Rev 09
Protocol Detail Sheet (PDS) Number: 201403119 Rev 01

Summary: The testing was conducted in accordance with EN 14683:2014, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

Results:
Bioburden: When bioburden results are calculated using a validated computer spreadsheet program, manual calculations may differ slightly due to rounding.

Unit Number	Test Article	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/g)
1	DQ006	2.5	<3	<3	<2.4
2	DQ007	2.8	<3	<3	<2.1
3	DQ008	2.6	<3	<3	<2.3
4	DQ009	2.3	<3	<3	<2.6
5	DQ010	2.8	<3	<3	<2.1
Recovery Efficiency		UTD			

Note: The results are reported as colony forming units (CFU) per mask.
< = No Organisms Detected
UTD = Unable to determine

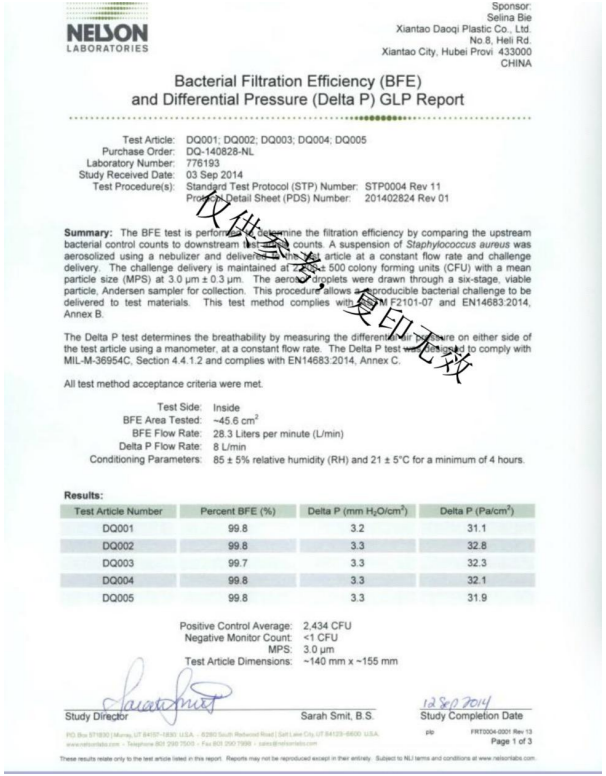
Acceptance Criteria: The data are reported by Nelson Laboratories, Inc. (NLI) and the sponsor performs any statistical analysis and determines the acceptance criteria.

Procedure:
Positive Controls/Monitors: *Bacillus atrophaeus*
Extract Fluid: Peptone Tween® with Sodium Chloride
Extract Fluid Volume: ~300 mL
Extract Method: Orbital Shaking for 5 minutes at 250 rpm
Plating Method: Membrane Filtration
Agar Medium: Tryptic Soy Agar
Sabouraud Dextrose Agar with Chloramphenicol
Recovery Efficiency: Exhaustive Rinse Method
Aerobic Bacteria: Plates were incubated 3 days at 30-35°C, then enumerated.
Fungal: Plates were incubated 7 days at 20-25°C, then enumerated.

Wendy Wangsgard
Study Director Wendy Wangsgard, Ph.D., RM(NRCM)

14/04/2014
Study Completion Date

FRT0036-0010 Rev 1
Page 1 of 2



NELSON LABORATORIES

Sponsor:
Selina Bie
Xiantao Daoqi Plastic Co., Ltd.
No.8, Heli Rd.
Xiantao City, Hubei Provi 433000
CHINA

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) GLP Report

Test Article: DQ001; DQ002; DQ003; DQ004; DQ005
Purchase Order: DQ-140828-NL
Laboratory Number: 776193
Study Received Date: 03 Sep 2014
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 11
Protocol Detail Sheet (PDS) Number: 201402824 Rev 01

Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 2 x 10^2 to 500 colony forming units (CFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM F2101-07 and EN14683:2014, Annex B.

The Delta P test determines the breathability by measuring the differential pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was performed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN14683:2014, Annex C.

All test method acceptance criteria were met.

Test Side: Inside
BFE Area Tested: ~45.6 cm^2
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours.

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
DQ001	99.8	3.2	31.1
DQ002	99.8	3.3	32.8
DQ003	99.7	3.3	32.3
DQ004	99.8	3.3	32.1
DQ005	99.8	3.3	31.9

Positive Control Average: 2,434 CFU
Negative Monitor Count: <1 CFU
MPS: 3.0 µm
Test Article Dimensions: ~140 mm x ~155 mm

Sarah Smit
Study Director Sarah Smit, B.S.

12/9/2014
Study Completion Date

FRT0004-0001 Rev 13
Page 1 of 3

POSI Certificate

POSI
波西认证

CERTIFICATE

The Certification Body of
Shanghai POSI certification Co., Ltd.
Hereby certifies that the organization

Xiantao Daoqi Plastic Co., Ltd.

Registered Address:No.83 Wagou New District,Pengchang Town,Xiantao City,Hubei Province,China
Audit Address: No.83 Wagou New District,Pengchang Town,Xiantao City,Hubei Province,China

Business license number: 91429004181667161H

has established and applied a quality management system for:

Production and sales of disposable medical mask,disposable medical cap(within the scope of the registration certificate);production and sales of non sterilized non-woven products(disposable surgical clothing,work clothes,bed sheets,shoe covers)and non sterilized plastic products(shoe covers,sleeve covers,aprons)(exports only)

audit was performed, proof has been furnished that the requirements according to

ISO13485:2016

are fulfilled.

Certificate Registration No：POSIMD00036
Initial issue date:2019.05.22　　Issue date: 2019.05.22　　Valid until:2022.05.21

General Manager

This certificate is issued by Shanghai POSI certification Co., Ltd., the certificate holder shall accept the surveillance audit by POSI. For obtaining the validity of certificate, please visithttp://www.posicert.com. the certificate information is also available on the CNCA official website: http://cx.cnca.cn.

Shanghai POSI Certification Co., Ltd.
Room 1002A, No.1500, Century Avenue, Pudong New District, Shanghai
Tel: +86-21-68583895 Email:info@posicert.com

POSI · 波西认证

POSI
波西认证

质量管理体系认证证书

兹证明

仙桃市道琦塑业股份有限公司
注册地址：湖北省仙桃市彭场镇挖沟新区83号
经营地址：湖北省仙桃市彭场镇挖沟新区83号

统一社会信用编码：91429004181667161H

建立了质量管理体系，所涉及的活动范围覆盖：

一次性使用医用口罩、一次性使用医用帽的生产和销售（注册证范围内）；非灭菌无纺布制品（一次性手术衣、工作服、床单、鞋套）及非灭菌塑料制品（鞋套、袖套、围裙）的生产和销售（仅限出口）。

经审核和评审，证明其质量管理体系符合下述标准要求：

ISO13485:2016

证书编号：POSIMD00036
首次发证日期：2019.05.22　本次发证日期：2019.05.22　有效期：2022.05.21

总经理

获证组织应按合同约定每年执行监督审核。认证证书是否有效可登陆 http://www.posicert.com 查询。
本证书由上海波西认证有限公司提供，该证书信息可在国家认证认可监督管理委员会官方网站 http://cx.cnca.cn 查询。

上海波西认证有限公司
上海世纪大道 1500 号 1002A
电话：+86-21-68583895　Email：info@posicert.com

POSI · 波西认证

FDA Registration

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

XIANTAO DAOQI PLASTIC CO., LTD.
No. 83 Wagou New District, Pengchang Town , Xiantao Hubei, CHINA,433018
has completed the FDA Establishment Registration (as manufacturer , contract manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA Communications: SUNGO TECHNICAL SERVICE INC.
6050 W EASTWOOD AVE APT 201, CHICAGO, ILLINOIS 60630, USA
Telephone: +1-855-957-7779 / E-mail: sungo.group@yahoo.com

Registration Number: 3011140825
Device Listing#: See annex

SUNGO Technical Service Inc. 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. SUNGO Technical Service Inc. 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. SUNGO Technical Service Inc. 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. SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.

Sungo FDA

Executive Director
Issued: Dec. 27 2019
Cert No.: 2006US81724
Expiration Date: Dec. 31 2020

SUNGO CHINA OFFICE Tel: 021-68828052 Email:Shage2008@126.com Website: www.sungoglobal.com
Add: 13th Floor, No.1500 Century Avenue, Shanghai 200122, P.R.China

Product Package Info

50Pcs / Box

Size: 18*10*8 cm

Material: non-woven

Color: Blue

Weight: 1lb

40Containers/ Carton (2000 Pcs)

50 Pcs per Container, 40 boxes per Carton

2000 Pcs per Carton

Carton Dimension: 52*38*34 cm

G. W.: 8 kg