欧代协议 EC-REP

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICAT

Sungo global service

To whom it may concern

SUNGO Europe B.V. located in Olympisch Stadion 24, 1076DE Amsterdam, Netherlands is appointed as the European Representative by XIANTAO SANDA INDUSTRIAL CO., LTD located in NO.46 GOLDEN AVENUE, XIANTAO, HUBEI, CHINA, 433000

The "Business Area" and "Product Categories" for the EU REP are Face Mask, Caps, Surgical Gown, Isolation Gown, Coverall, Patient Gown, Lab Coat, Shoe Covers, Bed sheet, Bed covers, Pillow Cases, Sleeve covers, Apron in Europe market. And the formal contact of SUNGO Certification Company Limited is as following:

Contact: SUNGO Secretary
Tel: +31 (0)20 21 11 106
E-mail: ec.rep@sungoglobal.com

Signature and Stamp
SUNGO Europe B.V.

SUNGO Sungo global service CERTIFIED

Issued: Jun. 5 2019
Expiration Date: Jun. 4 2024

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

CE 荷兰药监局注册

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

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Farmatec

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http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
J.I. van de Leuv

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20201759

Bijlagen
-

Uw aanvraag
29 april 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 15 mei 2020
Betreft: aanmelding medisch hulpmiddel klasse I

Geachte heer Luo,

Graag bevestig ik hierbij de ontvangst op 29 april 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf Xiantao Sanda Industrial CO., Ltd met Europees gemachtigde SUNGO Europe B.V. onderstaand medisch hulpmiddel, ingedeeld in risicoklasse I, aflevert. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende dit product het bijbehorende kenmerk te vermelden.

Disposable Medical Face mask
(geen merknaam) (NL-CA002-2020-50870)

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

Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling – verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Met name wijzen wij u op de Nederlandse-taaleis, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiesysteem.

CE 证书

European Commission

Verification of Conformity

Applicant:	XIANTAO SANDA INDUSTRIAL CO.,LTD
Address:	NO.46 GOLDEN AVENUE,XIANTAO,HUBEI,CHINA
Product(s):	Coverall, Lab Coat, Shoe Cover, Pillow Case, Sleeve Cover, Apron, Face Mask, Cap, Surgical Gown, Patient Gown, Isolation Gown, Bed Sheet/Bed Cover
Type(s):	See annex
Product Classification:	Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Medical Device Directive (93/42/EEC).

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

Standard(s): 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

The review result of the technical files and test report support the self declaration for the devices listed above. 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.

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CE Sungo global service

Executive Director
Issued: Dec. 10 2019
Cert. No.: EU158518
Expiration Date: Dec. 9 2024

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

FDA 证书

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

XIANTAO SANDA INDUSTRIAL CO.LTD
NO.46 GOLDEN AVENUE,XIANTAO,HUBEI,CHINA
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: 3008048818
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 global service FDA

Executive Director
Issued: Dec. 26 2019
Cert. No.: 2006US819518
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

Certificate of Registration

This is to certify that the Quality Management System of

XIANTAO SANDA INDUSTRIAL CO., LTD.

Unified Social Credit Code： 91429004730887731XN
Operation Address : No.46 East Section of Golden Avenue, Xiantao City, Hubei Province, China
Registered Address : No.46 East Section of Golden Avenue, Xiantao City, Hubei Province, China

applicable to

Manufacture and sales of PP non-woven series products (caps, shoes cover, sleeves, working clothing); production and sales of disposable medical masks (non-sterile)(within the scope of qualification license)

has been assessed and registered by NQA against the provisions of

ISO 9001:2015

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.
Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.
The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)
SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number **47672**

Date: 19 May 2020
Valid Until: 19 May 2023
EAC Code: 04

UKAS MANAGEMENT SYSTEMS 015

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.
NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.
This certificate is the property of NQA and must be returned on request.

NELSON2018 检测报告(ASTM)

Nelson Labs™
A Sotera Health company

Sponsor:
Mingmin Hu
Xiantao Sanda Industrial, Co., Ltd.
No. 46 HuangJin Ave. (East Section)
Xiantao, Hubei Province, 433000
CHINA

为0402-0788/1389示检

Latex Particle Challenge Final Report

Test Article:	SD20180308-1 SD20180308-2 SD20180308-3 SD20180308-4 SD20180308-5
Study Number:	1033510-S01
Study Received Date:	23 Mar 2018
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0005 Rev 05
Deviation(s):	None

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized, dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the average number of particles penetrating the test article compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 23% relative humidity (RH) at 1040; 20°C, 25% RH at 1403
Average Filtration Efficiency:	98.8%
Standard Deviation:	0.09

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Study Director Brandon L. Williams

04 Apr 2018
Study Completion Date

1033510-S01

SANDA三达

Nelson Labs
A Sotera Health company

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CHINA

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

2604-001788/1789备注:

Test Article:	SD20180308-1 SD20180308-2 SD20180308-3 SD20180308-4 SD20180308-5
Study Number:	1033509-S01
Study Received Date:	23 Mar 2018
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 15
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 2.7 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-14, EN 14683:2014, Annex B, and AS4381:2015.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C and AS4381:2015.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
BFE Test Area:	~40 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
Test Article Dimensions:	~160 mm x ~156 mm
Positive Control Average:	2.5 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

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Study Director — For Janelle R. Bentz, M.S.

02 APR 2018 Study Completion Date

1033509-S01