DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 080946 0012 Rev. 01

Holder of Certificate: **Anji SPENQ Industrial Co., Ltd.**
F16, Building C
Anji Chamber of Commerce Mansion
No. 99 Tianhuangping South Road
313300 Anji County, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Anji SPENQ Industrial Co., Ltd.
F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Medical Dressings, Medical Disposable Products and Medical Instruments**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1960110

Valid from: 2019-11-24
Valid until: 2022-11-23

Date, 2019-11-13

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

EC DECLARATION OF CONFORMITY

Manufacturer:
Name: Anji SPENQ Industrial Co., Ltd.
Address: F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China.
Tel: 0086-572-5882801 Fax: 0086-572-5676519

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

Manufacturing Sites:
F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China

Product Names: Face Mask

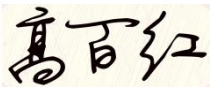
STANDARD:EN14683:2019

Relevant EC Directive: Medical Device Directive 93/42/EEC

Classification of products: Class I according to Annex IX of the Directive 93/42/EEC.
The products bear the mark.

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC . The above-mentioned declaration of conformity is exclusive under the responsibility of **Anji SPENQ Industrial Co., Ltd.**



Declaration person: Gao Baihong
Position: General Manager
Place: Anji City, China
Signature of issue person:
Date: May 18, 2020

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

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

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
J.I. van de Leuv

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20201334

Bijlagen
-

Uw aanvraag
10 april 2020

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

Datum: 24 april 2020
Betreft: aanmelding medisch hulpmiddel klasse I

Geachte heer Luo,

Graag bevestig ik hierbij de ontvangst op 10 april 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf Anji SPENQ 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.

Medical face mask
(geen merknaam) (NL-CA002-2020-50418)

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.

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

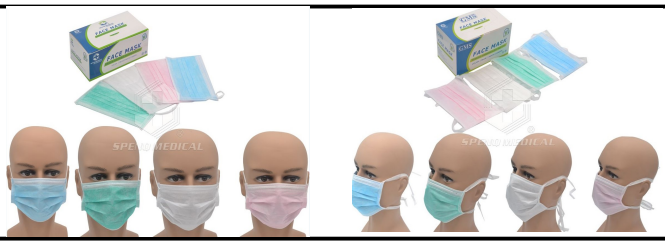
Dr. M.J. van de Velde

Dhr. M.J. van de Velde

SPENQ MEDICAL GROUP CORPORATION LIMITED
ANJI SPENQ INDUSTRIAL CO., LTD. / ANJI JIXIANG MEDICAL CO., LTD.
ADD: TANGPU ECONOMIC DEVELOPMENT ZONE, ANJI, ZHEJIANG, CHINA.
TEL: +86-572-5882801 FAX: +86-572-5882115 WWW.SPENQ.COM

PRODUCT SPECIFICATION

PART I. PRODUCT IDENTIFICATION

Brand	**SPENQ MEDICAL®**
Code No.	**MF050101**
Product Name	**Medical Face Mask**
Type	EN 14683 : 2019, Type II
Type	Earloops Type; Ties On Type
Color	Blue color, Green color, white color, pink color, etc.
Material	2ply PP non-woven + 1ply meltblown fabric
Weight	3ply: 25 + 25 + 25 G/M2
Key Parameter	1.Bacterial Filtration Efficiency (BFE): ⩾ 98%
	2.Differential pressure: ≤ 29.4 Pa/cm2
	3.Microbial cleanliness: ≤ 30 cfu/g
Applications	It's especially used for designed for the medical personal protection.
Type of Product	Medical disposable
Sterilization Method	Non-sterile
Storage Instruction	Store in dry, ventilative condition, with ordinary temperature.
Picture	

PART II. QUALITY SYSTEM & STANDARD

Classification	Class I (non-sterile)
Standard	EN 14683 : 2019
Quality Management Systems & No.	ISO13485
	Q6 080946 0012 Rev. 01

Production Quality Assurance System & No.	Declaration of Conformity
	———
CE Conformity Assessment Route	MDD 93/42/EEC Annex VII (Self Declaration)
Certification Body	TUV SUD Product Service GmbH
U.S. FDA Registering No.	3007694982
Listing Number	D366504

PART III. PACKAGING INFORMATION

Size	**Individual Packaging**		**Secondary Packaging**		**Outer Packaging**		
	Qty	**Material**	**Qty**	**Material**	**Qty**	**Dimensions**	**Material**
Earloops Type	—	—	50	paper box	2000	52x38x34cm	carton
Ties On Type	—	—	50	paper box	2000	52x38x44cm	carton

CMA
160920340809

检 测 报 告
(Test Report)

No. BOYASLER823697L1

样品名称 (Sample Description)	医用口罩 Medical Face Mask
委托单位 (Applicant)	安吉鑫沣进出口有限公司 Anji SPENQ Industrial Co.,Ltd

PONY 谱尼测试
Pony Testing International Group

声 明
Statement

1. 本报告无专用章和批准人签章无效。
This report is invalid without the approver's signatures and special seal of inspection.

2. 本报告页面所使用“PONY”、“谱尼”字样为本单位的注册商标，其受《中华人民共和国商标法》保护，任何未经本单位授权的擅自使用和仿冒、伪造、变造“PONY”、“谱尼”商标均为违法侵权行为，本单位将依法追究其法律责任。
The pattern and characters of "PONY" and "谱尼" used in this report are protected by the trademark law of the People's Republic of China. Any unauthorized usage, counterfeit, forgery and alteration of trademarks of "PONY" and "谱尼" are the violations of the law. The PONY has the right to pursueall legal liabilities of the subject of the delict.

3. 委托单位对报告数据如有异议，请于报告完成之日起十五日内（初级农产品报告请于报告收到之日起五日内）向本单位书面提出复测申请，同时附上报告原件并预付复测费。
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. 委托单位办理完毕以上手续后，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.

5. 不可重复性或不能进行复测的实验，不进行复测，委托单位放弃异议权利。
Tests that can not be repeated and tested shall not be carried out again.

6. 委托单位对样品的代表性和资料的真实性负责，否则本单位不承担任何相关责任。
The applicant should undertake the responsibility for the provided samples' representativeness and document authenticity. Otherwise, PONY has not any relevant responsibilities.

7. 本报告仅对所测样品负责，报告数据仅反映对所测样品的评价，对于报告及所载内容的使用、使用所产生的直接或间接损失及一切法律后果，本单位不承担任何经济和法律责任。
This report is only responsible for the provided sample. The test results only represent the evaluation of the tested sample. PONY will not be responsible for any economical or legal liability generated from direct or indirect usage of the test report.

8. 本单位有权在完成报告后处理所测样品。
PONY has the right to dispose the tested sample after approval of the test report.

9. 本单位保证工作的客观公正性，对委托单位的商业信息、技术文件等商业秘密履行保密义务。
PONY assures objectivity and impartiality of the test, and fulfills the obligation of confidentiality for applicant's commercial information, and technique document.

10. 本报告私自转让、盗用、冒用、涂改、未经本单位批准的复制（全文复制除外）或以其它任何形式的篡改均属无效，本单位将对上述行为严究其相应的法律责任。
The report is invalid in case of illegal transfer, embezzlement, imposture, modification or any altering, reproducing except in full, without approval of PONY. PONY shall investigate and affix the applicant's legal liability accordingly.

▲防伪说明(Anti-counterfeiting Description)：

(1) 报告编号是唯一的；
The test report has exclusive report code.

(2) 报告采用特制防伪纸张印制，纸张表面带有"PONY"防伪纹路，该防伪纹路不支持复印，即复制件不会带有"PONY"防伪纹路。
The test report is printed by anti-copying paper whose surface shows "PONY" security print with specific anticounterfeiting technique. Security print will disappear after copying. Duplicates are not expected to give "PONY" security print under any circumstances.

全国服务热线
400-819-5688
WWW.PONYTEST.COM

扫描二维码
关注谱尼测试微信公众号
PONY4008195688

北京实验室：(010) 83055000　武汉实验室：(027) 83997127　哈尔滨实验室：(0451)58627755
上海实验室：(021) 64851999　长春实验室：(0431)85150908　石家庄实验室：(0311)85376660　温州实验室：(0577)88271060
青岛实验室：(0532)88706866　大连实验室：(0411)87336618　乌鲁木齐实验室：(0991) 6684186　合肥实验室：(0551)63843474
深圳实验室：(0755)26050909　郑州实验室：(0371)69350670　呼和浩特实验室：(0471) 3450025　广州实验室：(020) 89224310
天津实验室：(022) 23607888　西安实验室：(029) 89608785　杭州实验室：(0571)87219096　厦门实验室：(0592)5568048
苏州实验室：(0512)62997900　太原实验室：(0351) 7555762　宁波实验室：(0574)87736499　成都实验室：(028) 87702708

PONY 谱尼测试
Pony Testing International Group

检测结果
(Test Results)

No. BOYASLER823697L1

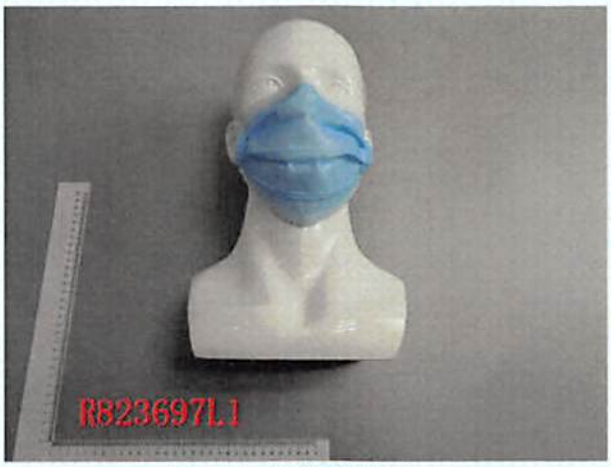
样品名称 (Sample Description)	医用口罩 Medical Face Mask	样品规格 (Sample Specification)	规格 Specification：17.5×9.5cm 型号 Model：3plys
委托单位 (Applicant)	安吉鑫沣进出口有限公司 Anji SPENQ Industrial Co.,Ltd	商标 (Trade Mark)	——
到样日期 (Received Date)	2020-03-26	生产日期或批号 (Manufacturing Date or Lot No.)	生产日期 Manufacturing Date：2020.03 生产批号 Manufacturing Lot No.：20200318
检测日期 (Test Date)	2020-03-26~2020-04-09	样品等级 (Sample Grade)	——
样品数量 (Sample Quantity)	50 只 50pcs	检测类别 (Test Type)	委托检测 (Commissioning Test)
样品状态 (Sample Status)	正常 Nomal	检测环境 (Test Environment)	符合要求 (To meet the requirements)
检测项目 (Test Items)	见下页 See the next page		
检测方法 (Test Methods)	见下页 See the next page		
所用主要仪器 (Main Instruments)	电热恒温培养箱 Electric Heating Constant Temperature Incubator、 细菌过滤效率检测仪 Bacterial filtration efficiency detector 等 etc		
备注 (Note)	限值标准 Limit Standard：EN 14683：2019 样品来源 Sample Source：工厂送检 Factory Inspection 生产单位 Production：安吉鑫沣进出口有限公司 Anji SPENQ Industrial Co.,Ltd 受检单位 Inspection：安吉鑫沣进出口有限公司 Anji SPENQ Industrial Co.,Ltd		
PONY 专用章 (Special Stamp of PONY)	编制人 (Edited by)		
	审核人 (Checked by)		
	批准人 (Approved by)		
	签发日期 (Issued Date)	2020-04-09	

检 测 结 果
(Test Results)

No. BOYASLER823697L1

样品名称和编号 (Sample Description and Number)	检测项目 (Test Items)	限值 (Limit)			检测结果 (Test Results)		检测方法 (Test Methods)
		I 型 Type I	II 型 Type II	II R 型 Type II R			
R823697L1 医用口罩 Medical Face Mask	细菌过滤效率 (BFE)，% Bacterial filtration efficiency(BFE)	≥95	≥98	≥98	No.1	98.9	EN 14683：2019
					No.2	98.5	
					No.3	99.1	
					No.4	98.9	
					No.5	98.8	
	压力差，Pa/cm^2 Differential pressure	<40	<40	<60	21.6		EN 14683：2019
	抗溅压力，kPa Splash resistance pressure	/	/	≥16.0	>16.0		EN 14683：2019
	微生物清洁度，cfu/g Microbial cleanliness	≤30	≤30	≤30	1		EN 14683：2019

样品编号和照片（Sample Number and Photo）：



仅对报告照片中的样品负责

Pony authenticate the photo on original report only

———以下空白———

(End of Report)