Disposable EN 14683 MONDMASKER

APRIL 2020

- 1. Tuv EC + CE Certificering
- 2. Testresultaten referent aan bovenstaande certificering TuV (vertaald)
- 3. Testresultaten referent aan bovenstaande certificering TuV (orgineel)









EC Certificate Directive 93/42/EEC Annex V Production Quality Assurance Medical Devices

Registration No.: DD 60148626 0001

Report No.: 15084642 009

Manufacturer: Shanghai

Shanghai Xiangchi Health

Products Co., Ltd.

No. 755 Yuejin Village, Shuxin Town

Chongming County 202157 Shanghai

P.R. China

Products: Medical Devices

(see attachement for products included)

Replaces Approval, Registration No.: DD 60104284 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this

certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-04-10

Date: 2020-04-10

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

Notified Body

TOTALD I GAIDS B. TOY TUEY and TUY are reported trademarks. Utilization and application requires prior approve



Doc. 1/1, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.:

DD 60148626 0001

Report No.:

15084642 009

Manufacturer:

Shanghai Xiangchi Health

Products Co., Ltd.

No. 755 Yuejin Village, Shuxin Town

Chongming County 202157 Shanghai

P.R. China

Products:

- Alcohol Pads

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Disposable Medical Face Masks
- Disposable Medical Caps
- Disposable Shoe Covers
- Disposable Surgical Gowns

Date: 2020-04-10

Notified Body

Jason Pan

Notified Body

Jason Pan

TEST REPORT

Medical fa	Medical face mask								
165x90mm									
SHANGHAI XINGCHI HEALTH PRODUCTS CO., LTD									
SHANGHAI XINGCHI HEALTH PRODUCTS CO., LTD									
NO. 1800439			Date		2020/3/12	20/3/12			
2020/3/12			Sample quantity		20 pcs	20 pcs			
Poly bag packing, blue color, well status, Room temperature preservation									
No. 2525, Hangzhouwan road, Jinshan area, Shanghai									
GB 15979-2002									
Report according sandard YY 0469-2011									
te From March 12, 2020 to March 19, 2020									
	SHANGHAI SHANGHAI NO. 18004 2020/3/12 Poly bag pa No. 2525, I GB 15979- sandard	165x90mm SHANGHAI XINGCHI HEALTH PROD SHANGHAI XINGCHI HEALTH PROD NO. 1800439 2020/3/12 Poly bag packing, blue color, well s No. 2525, Hangzhouwan road, Jins GB 15979-2002 sandard YY 0469-2011	165x90mm SHANGHAI XINGCHI HEALTH PRODUCTS CO SHANGHAI XINGCHI HEALTH PRODUCTS CO NO. 1800439 2020/3/12 Poly bag packing, blue color, well status, Ro No. 2525, Hangzhouwan road, Jinshan area, GB 15979-2002 sandard YY 0469-2011	SHANGHAI XINGCHI HEALTH PRODUCTS CO., LTD SHANGHAI XINGCHI HEALTH PRODUCTS CO., LTD NO. 1800439 Date 2020/3/12 Poly bag packing, blue color, well status, Room temperary No. 2525, Hangzhouwan road, Jinshan area, Shanghai GB 15979-2002 sandard YY 0469-2011	SHANGHAI XINGCHI HEALTH PRODUCTS CO., LTD SHANGHAI XINGCHI HEALTH PRODUCTS CO., LTD NO. 1800439 Date 2020/3/12 Poly bag packing, blue color, well status, Room temperature properties of the product	165x90mm SHANGHAI XINGCHI HEALTH PRODUCTS CO., LTD SHANGHAI XINGCHI HEALTH PRODUCTS CO., LTD NO. 1800439 Date 2020/3/12 Poly bag packing, blue color, well status, Room temperature preservation No. 2525, Hangzhouwan road, Jinshan area, Shanghai GB 15979-2002 sandard YY 0469-2011	SHANGHAI XINGCHI HEALTH PRODUCTS CO., LTD SHANGHAI XINGCHI HEALTH PRODUCTS CO., LTD NO. 1800439 Date 2020/3/12 Sample quantity 20 pcs Poly bag packing, blue color, well status, Room temperature preservation No. 2525, Hangzhouwan road, Jinshan area, Shanghai GB 15979-2002 sandard YY 0469-2011		

	Test result							
No.	Test item	Unit	Requirements	Testing way	Result			
1	Bacterial colonies	CFU/g	<100	GB 15979-2002	<4	Pass		
2	Coliform	/	N/A	GB 15979-2002	N/A	Pass		
3	Pseudomonas Aeruginosa	/	N/A	GB 15979-2002	N/A	Pass		
4	Staphylococcus aureus	/	N/A	GB 15979-2002	N/A	Pass		
5	Streptococcus haemolyticus	/	N/A	GB 15979-2002	N/A	Pass		
6	Funqal colony	/	N/A	GB 15979-2002	N/A	Pass		









兹证明

玉川卫生用品(上海)有限公司

统一社会信用代码: 91310000764735066N

经营地址: 上海市金山区金山工业区林慧路 666 号注册地址: 上海市金山区金山工业区林慧路 666 号

的质量管理体系适用于

非灭菌一次性医用无纺布口罩的生产(出口至日本)

已经 NQA 根据标准

ISO 13485: 2016

审核和注册

注册要求组织必须按照上述标准保持其质量管理体系,并由 NQA 进行监督。 获证组织必须定期接受监督审核并经审核合格,此证书方继续有效。 本证书信息可在国家认证认可监督管理委员会官方网站(www. cnca. gov. cn)上查询 SNQA 查询网站: www. snqa. com. cn

Nungur

Managing Director



Certificate Number

Date: Reissue Date: Valid Until: EAC Code: 29097

11 September 2013 30 November 2018 30 November 2021 04

