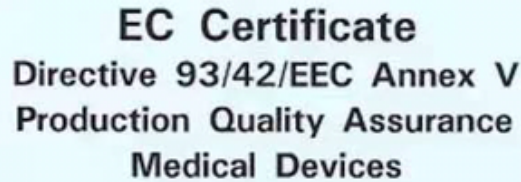


Disposable EN 14683 MONDMASKER

APRIL 2020

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





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.

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



TEST REPORT

Sample name	Medical face mask				
Specification	165x90mm				
Supplier	SHANGHAI XINGCHI HEALTH PRODUCTS CO., LTD				
Producer	SHANGHAI XINGCHI HEALTH PRODUCTS CO., LTD				
Order number	NO. 1800439		Date	2020/3/12	
Sample date	2020/3/12		Sample quantity	20 pcs	
Status	Poly bag packing, blue color, well status, Room temperature preservation				
Testing address	No. 2525, Hangzhouwan road, Jinshan area, Shanghai				
Test basis	GB 15979-2002				
Report according sandard		YY 0469-2011			
Testing date	From March 12, 2020 to March 19, 2020				

		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	Fungal 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

Managing Director



Certificate Number

29097

Date:

Reissue Date:

Valid Until:

EAC Code:

11 September 2013

30 November 2018

30 November 2021

04

