

Declaration of Conformity

Manufacturer: Xiamen Langxing Energy Saving Lighting Co., Ltd.
591 Tonglong Rd. (No. 2), Torch (Xiang'an) Industrial Zone,
tong'an district, Xiamen, Fujian, China

whose single *Luxus Lebenswelt GmbH*
Authorized EU- *Kochstr.1, 47877, Willich, Germany*
Representative: *DIMID: DE/0000047791*
 Lin Sun
 Tel: 0049-1715605732
 E-mail: info.m@luxuslw.de

Product Name: Disposable Medical masks
Disposable Protective masks



Classification: I of ANNEX IX of Directive 93/42/EEC

Conformity Assessment Route: following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

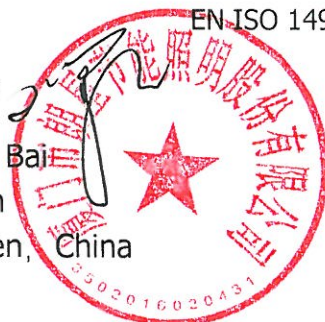
We here declared that above mentioned product met the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General Applicable Directives:
Medical Devices DIRECTIVE

Harmonized Standards:

EN ISO 13485:2016 EN ISO 10993 EN 980-2003
EN 14683 EN ISO 14971-2007

Signature: 
Name: Luming Bai
Title: Chairman
Position: Xiamen, China





SUBJECT Physical & Microbiological Test

TEST LOCATION TÜV SÜD China

TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai 201108, P.R. China

CLIENT NAME Xiamen Langxing Energy Saving Lighting Co., Ltd.

CLIENT ADDRESS 591 Tonglong Rd. (No. 2), Torch (Xiang'an) Industrial Zone, tong'an district,
Xiamen, Fujian, China

TEST PERIOD 16-Apr-2020~03-May-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By



(Leo Liu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested. (3) The test report shall not be reproduced except in full without the written approval of the laboratory. (4) Without the agreement of the laboratory, the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co.,
Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing
(China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

TÜV[®]

TEST REPORT

Sample Description : Disposable medical masks
Sample Quantity : 50 pieces
Lot Number/Batch Code : 20200402
Specification : LX-DSM01
Size : /
Brand Name : /

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Method	Test Standard Type I	Judgement
1	Bacterial Filtration Efficiency Test (BFE), %	EN 14683:2019+AC:2019(E) Annex B	≥ 95	Pass
2	Differential Pressure Test (Pa/cm ²)	EN 14683:2019+AC:2019(E) Annex C	<40	Pass
3	Microbial Cleanliness Test (CFU/g)	EN 14683:2019+AC:2019(E) Annex D	≤ 30	Pass

Note: Pass = Meet customer requirements;

Fail = Fail customer requirements;

= No comment;

N.D. = Not detected.

Photo of Samples

