

CERTIFICATE

With EU Directive of Medical Device Directive (MDD 93/42/EEC)

Certificate No.: CE-20-0303-01

Holder: Sichuan Heng Ming Technology Development Co., Ltd.
No.39,Jingqixi Road,Tianpeng Town, Pengzhou Industrial
Development Zone, Sichuan Province (Postcode: 611930)

Product: Disposable Isolation Clothes
Medical Disposable Face Masks
Surgical Mask
Medical Glove

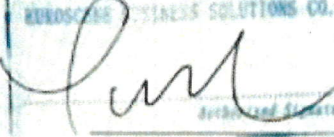
Standards: EN ISO 13485:2016/AC:2016,EN ISO 14971:2012,EN ISO
15223-1:2016,EN 1041:2008,EN ISO 10993-1:2009/AC:2010,
EN 14683:2019,EN 455-1:2000,EN 455-2:2009+A2:2013

Based upon the voluntary assessment of the product sample and Technical Construction File, the apparatus is deemed to meet the requirements of the above standards and EC directives.

The manufacturer has the responsibility for ensuring that all serial manufacture of the products are in compliance with the specification of the sample submitted for assessment and detailed in the technical file.



Date: Mar.03.2020

Certification Body
For and on behalf of
EUROSCENE BUSINESS SOLUTIONS CO.,LTD

Authorized Signature in
Euroscene Business Solutions

The CE marking may be used if all relevant and effective EC directives are complied with.

Euroscene Business Solutions Limited
Flat 3,The picture house,195 darkes Lane,Potters Bar,Herts, EN6 1BP

Maska antibakteriálna s gumičkou

Popis :

- Trojvrstvová antibakteriálna maska
- Vysoká filtračná schopnosť
- Hypoalergénna
- Umožňuje výbornú anatomickú tvarovateľnosť vďaka integrovanej výstuži
- Bez zápachu



3 vrstvy / plies

50 ks / psc

BFE 99,7%

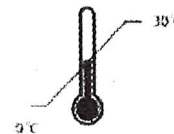
EN 149:2001+A1:2009

Typ II / type II

REF 702510016

LOT 20190220

2024-02



ZIPP OFFICE PARK s.r.o.

Stará Vajnorská 17, Bratislava III



Jiangying Jieyi Electronic Co., Ltd.
555 Qinfeng Road, Huashui Zhen, Čína

Dodávateľ:

Faktura č.:D20200036 Dod.List č.:203/20/00

Oullins s.r.o.

Slávičie údolie 10
811 02 Bratislava
Slovak Republic
IČO:51791226
DIČ:2120783093
IČ DPH:SK2120783093

Dátum vystavenia: 06.07.2020
Dátum dodania: 06.07.2020
Variabilný symbol: D20200036
Dátum splatnosti: 16.07.2020

Odberateľ:

Diafit d.o.o.

Spodnji Slemen 6,
2352 Selnica ob Dravi
Slovenia

IČO: DIČ:SI25646460
IČ DPH:

Banka:Tatra
Účet:SK83 1100 0000 0029 4507 9642
Tel.:
Fax.:
O.register:s.r.o.
Vložka č.:129456/B

p.č. kod	Pomenovanie	Názov	Cena(bez DPH)	Počet	Celkom
1	8584156004102	ruska 50pc	0.18	50000.0	9000.00

Základ pre DPH:		9000.00€
Suma DPH:	0 %	0.00€
Celková faktúrovaná suma:		9000.00€

Vystavil:BOSS
Dňa:

Poznámka: DO ZAHRANIČIA!

Oullins s. r. o.
Slávičie údolie 10, 811 02 Bratislava
IČO: 51 791 226
DIČ: 2120783093



Declaration of Conformity

Manufacturer: Wuxi Yushou Medical Appliances Co., Ltd
No.115, Nongxinhe Road, Xishan District, 214191 Wuxi
City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA
European Representative: Shanghai International Holding Corp. GmbH (Europe)
Product Name: Eiffestrasse 80, 20537 Hamburg, Germany
Product Type: Face Mask for Single Use
Type I, Type II, Type IIR
UMDNS Code: 12447
Registration number: DE/CA05/MP-238321-2762-00

Classification (MDD Annex IX): I, rule 1

Conformity Assessment Route: Annex VII of MDD93/42/EEC

We herewith declare that the above mentioned products meet 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. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

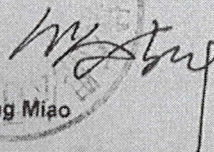
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC
The product complies with the following harmonized standard: EN14683:2019

EN ISO 13485-2016 Certification No.: Q60450840037 Rev:04

Expire date of the Certificate: 2023-4-30

Place, Date of Issue: Wuxi, 2020-05-14

Signature:

 2020.5.14.

Name: Mr. Liping Miao

Position: General Manager



TEST REPORT

Face Masks For Sing Use

50 pieces
 2003006

17.5 X 9.5cm

Type IIR

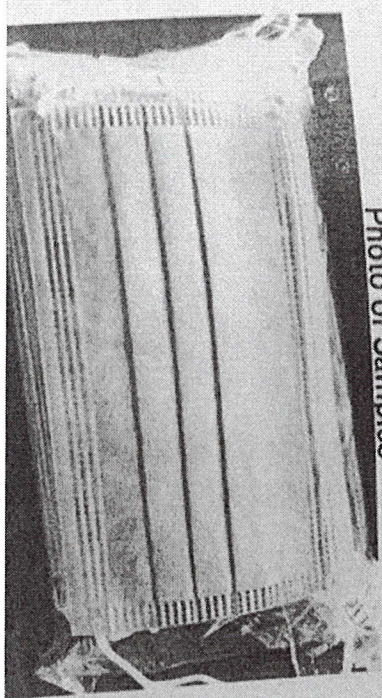
Sample Description
 Sample Quantity
 Sample/Batch Code
 Lot Number
 Specification
 Size of Mask
 Type of Mask
 Brand Name
 Remark: The above information was provided by applicant

Summary of Test Results

Test Item	Test Standard	Judgement
Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C ISO 22609:2004	Pass
Synthetic Blood Penetration Test	EN 14683:2019+AC:2019(E) Annex D	Pass
Microbial Cleanliness Test		Pass

Pass = Meet customer requirements.
 Fail = Fail customer requirements.
 ND = Not detected

Photo of Samples



Test Report No.: 721653433
Report Date: 16 April 2020



SUBJECT Physical & Microbiological Test

TEST LOCATION TÜV SÜD China

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

CLIENT NAME Wuxi Yushou Medical Appliances Co., Ltd

CLIENT ADDRESS No. 115, Nongxinhe Road, Xishan District, 214191 Wuxi City, Jiangsu Province,
PEOPLE'S REPUBLIC OF CHINA

TEST PERIOD 01-Apr-2020~10-Apr-2020

Prepared By

Authorized By

Bella Xu

(Bella Xu)
Report Drafter

Leo Liu

(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
200070 P.R. China

