



Prohlášení o shodě zdravotního prostředku.

Dovozce:

umbrellaline 2010 s.r.o.

IČO: 03874851 DIČ: CZ03874851

Ostrava, Mariánské Hory, Kopaniny 917/10, 709 00

zapsané u Krajského soudu v Ostravě, oddíl C, vložka 61686

Popis výrobku:

RespiLab™ - Jednorázové zdravotnické roušky (50ks)

RespiLab™ - Jednorázové zdravotnické roušky (10ks)

RespiLab™ - Jednorázové zdravotnické roušky (50ks), Black

RespiLab™ - Jednorázové zdravotnické roušky (10ks), Black

Výrobce

GANZHOU ZHUANGYUANLANG SANITARY PRODUCTS CO., LTD.

THE NO. 4 BUILDING, STANDARD WORKSHOP PHASE I, CHANCHENG NEW DISTRICT, ANYUAN

COUNTY, GANZHOU CITY, JIANGXI PROVINCE, Čína



Zplnomocněný zástupce zdravotního prostředku EC REP

CMC Medical devices & Drugs S.L

C/ Horacio Lengo n18 C.P 29006, Španělsko

Datum prohlášení:

2.11.2020

Zboží bylo testováno nezávislými akreditovanými zkušebními laboratořemi dle níže uvedených příslušných norem.

Použité normy:

EN 14683:2019, ISO 13485:2016

Eduard Rojíček

Vedoucí nákupního oddělení

Tento dokument byl přeložen, originál zobrazen níže, veškerá odpovědnost vyhrazena zplnomocněnému zástupci pro Evropu společnosti: (EC|REP) CMC Medical devices & Drugs S.L, Španělsko.

Originální dokument: Zplnomocněný zástupce

EC REP CERTIFICATE



CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/21082020.8

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

GANZHOU ZHUANGYUANLANG SANITARY PRODUCTS CO., LTD.
THE NO. 4 BUILDING, STANDARD WORKSHOP PHASE I, CHANCHENG NEW DISTRICT, ANYUAN COUNTY, GANZHOU CITY, JIANGXI PROVINCE

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number RPS/1982/2020



Issued on: 21/08/2020

Authorized Signatory
CMC Medical Devices & Drugs SL

Valid until: 20/08/2021

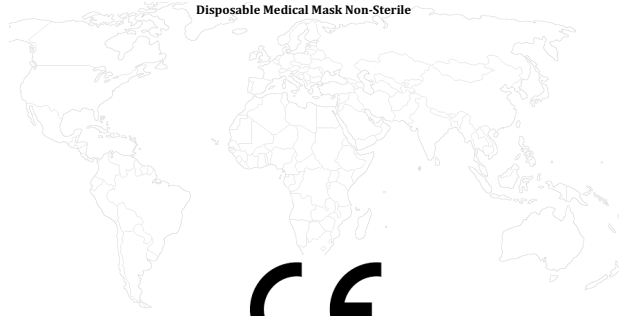
www.cmcmedicaldevices.com

EC REP CERTIFICATE



ANNEX I Medical Device Product

Disposable Medical Mask Non-Sterile



www.cmcmedicaldevices.com

Originální dokument: Prohlášení o shodě

EC Declaration of Conformity

Manufacturer: GANZHOU ZHUANGYUANLANG SANITARY PRODUCTS CO., LTD.

whose single Authorized EU-Representative:

CMC Medical Devices & Drugs S.L.
Horacio Lengo Nº 18, CP 29006, Málaga, Spain.

CMC Medical Devices & Drugs S.L.
Horacio Lengo Nº 18, CP 29006, Málaga, Spain.

THE NO. 4 BUILDING, STANDARD WORKSHOP PHASE I, CHANCHENG NEW DISTRICT, ANYUAN COUNTY, GANZHOU CITY, JIANGXI PROVINCE

We, the manufacturer, herewith declare that the products

Disposable medical mask (non sterile)

ZYL2050

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



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

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

GANZHOU ZHUANGYUANLANG SANITARY PRODUCTS CO., LTD.

EC Declaration of Conformity

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THE NO. 4 BUILDING, STANDARD WORKSHOP PHASE I, CHANCHENG NEW DISTRICT, ANYUAN COUNTY, GANZHOU CITY, JIANGXI PROVINCE

Place, date *Li Kanghui*



Legally binding signature. Function

EC Declaration of Conformity

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Test Report

(Electronic version)

Verification Website: www.gtcc.net.cn

Verification Code: NBKW-2412-44

No:20R001911

Issue Date: 2020-06-08

Applicant: GANZHOU ZHUANGYUANLANG SANITARY PRODUCTS CO., LTD.
Address: THE NO. 4 BUILDING, STANDARD WORKSHOP PHASE I, CHANCHENG NEW DISTRICT,
ANYUAN COUNTY, GANZHOU CITY, JIANGXI PROVINCE

Information confirmed by applicant:

Disposable medical mask(non-sterile)

Quantity: 60 pieces

Type: ZYL2050

Manufacture's name: GANZHOU ZHUANGYUANLANG SANITARY PRODUCTS CO., LTD.

Classification: Type II R

Standard Adopted:

EN 14683:2019+AC:2019 <Medical face masks-Requirements and test methods>

Date Received/Date Test Started: 2020-05-26

Conclusion:

Bacterial filtration efficiency (BFE) M

Microbial cleanliness M

Differential pressure M

Splash resistance pressure M

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "---"-No comment

Remark:

All the tested items are tested under the standard condition (except for indication).

Copies of the report are valid only re-stamped.

The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.

Approved By:

WanLi Hu Engineer

WanLi Hu



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RespiLION.cz

50KS

RespiLAB™

Zdravotnická třívrstvá
jednorázová rouška



Rouška třídy I, dle normy EN14683:2019
Otestováno v certifikované laboratorii v Evropě.
Vyrobeno v Číně