AC 114

CERTYFIKAT BADANIA TYPU UE (MODUŁ B)
EU TYPE-EXAMINATION CERTIFICATE (MODULE B)

Nr / *No.* CW/PPER/48/05/2020

ZAŚWIADCZA SIĘ,
że Polski Rejestr Statków S.A. (PRS) przeprowadził procedurę badania typu wymienionego niżej wyrobu i stwierdził jego zgodność z wymaganiami określonymi w załączniku V do Rozporządzenia Parlamentu Europejskiego i Rady (UE) 2016/425 (PPE) w sprawie środków ochrony indywidualnej oraz uchylenia dyrektywy Rady 89/686/EWG, ze zmianami.

THIS IS TO CERTIFY
that Polski Rejestr Statków S.A. (PRS) did undertake the EU type-examination procedure for the product identified below which was found to be in compliance with the requirements of Annex V to the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC, as amended.

Wnioskodawca / *Applicant*
Wenzhou Meiyi Medical Device Co., Ltd.
Hengjie Industrial, Xianjiang Street,
Ruian Wenzhou, Zhejiang, China.

Producent / *Manufacturer*
Wenzhou Meiyi Medical Device Co., Ltd.
Hengjie Industrial, Xianjiang Street,
Ruian Wenzhou, Zhejiang, China.

Typ wyrobu / *Product type*
Sprzęt ochrony dróg oddechowych. Sprzęt ochrony dróg oddechowych bez zasilania powietrzem. Półmaska filtrująca chroniąca przed COVID-19.
Respiratory protective equipment. Non-powered air-purifying particle respirator.
Filtering hakf mask to protect against COVID-19.

Opis wyrobu / *Product description*
Maska ochronna na twarz typ (KN95) MY-002 klasy FFP-2
3D facial protective mask type (KN95) MY-002 class FFP-2

Zastosowane normy / *Specified standards*
PN-EN 149 + A1:2010 oraz Rekomendacja RFU PPE-R/02.075 wersja 1.
EN-149:2001 + A1:2009 and Recommendation For Use PPE-R/02.075 version 1.

Niniejszy certyfikat pozostaje ważny do czasu unieważnienia przy zachowaniu warunków uznania (patrz str. 2).
This certificate remains valid unless cancelled or revoked, provided the approval conditions (see page 2) are complied with.

Data ważności / *Expiry date* 2021-05-26

Dyrektor Pionu Certyfikacji
Certification Division Director

Przemysław Gałka

Gdańsk, 2020-05-27

NOTIFIED BODY NO 1463

CE 1463

Nr jednostki notyfikowanej / *No. of notified body*

Polski Rejestr Statków S.A.
al. Gen. Józefa Hallera 126
80-416 Gdańsk, Poland

tel. (+48) (58) 346 17 00
fax (+48) (58) 341 77 69
e-mail: dc@prs.pl
www: http://www.prs.pl/

AC 114

CERTYFIKAT ZGODNOŚCI Z TYPEM W OPARCIU O WEWNĘTRZNĄ KONTROLĘ PRODUKCJI ORAZ NADZOROWANE KONTROLE PRODUKTU W LOSOWYCH ODSTĘPACH CZASU (Moduł C2)

CONFORMITY TO TYPE CERTIFICATE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS (Module C2)

Nr / *No.* CW/PPER/52/06/2020

Okres objęty certyfikatem / *Period covered by the certificate* 2020-06-16 – 2021-06-15

Dokumenty odniesienia: / *General reference documents:* Rozporządzenie UE 2016/425 dotyczące środków ochrony indywidualnej (PPE), załacznik VII / *Regulation (EU) 2016/425 on personal protective equipment (PPE), Annex VII*

Posiadacz certyfikatu / *Certificate holder*
Wenzhou Meiyi Medical Device Co., Ltd.
Hengjie Industrial, Xianjiang Street,
Ruian Wenzhou, Zhejiang, China.

Wyrób / *Product*	Certyfikat badania typu UE / *EU Type-examination certificate*	Normy zharmonizowane/Specyfikacje / *Harmonised standards/Specifications*
Maska ochronna na twarz typ (KN95) MY-002 klasy FFP-2 *3D facial protective mask type (KN95) MY-002 class FFP-2*	CW/PPER/48/05/2020	*PN-EN 149 + A1:2010.* *EN-149:2001 + A1:2009*

A **Roczna ocena zgodności wyrobów z normą/specyfikacją i badanym typem**
Annual assessment of products compliance with standard/specification and type-examined

1 Miejsca i daty wizyt / *Visit locations and dates* ----

2a Wyboru dokonał (imię, nazwisko) / *Selection carried out by (Name)* ----
Związek z jednostką notyfikowaną / *Relationship to notified body* ----

2b Przedstawiciel firmy (imię, nazwisko) / *Company representative (Name)* ----
Stanowisko / *Position* ----

3 Związek pomiędzy wizytowaną firmą a posiadaczem certyfikatu badania typu UE
Relationship of company visited to EU type examination certificate holder
☐ Posiadacz certyfikatu / *Certificate holder* ☐ Miejsce produkcji / *Production site* ☐ Inne miejsce produkcji / *Secondary production site* ☐ Importer / *Importer* ☐ Dystrybutor / *Distributor*
☐ Sprzedaż detaliczna / *Retail outlet* ☐ Europejskie biuro firmy / *European office of the company* ☐ Inny: / *Other:*
Wykaz środków ochrony indywidualnej / *List of personal protection equipment* ☐ Dostępny / *Available* ☐ Niedostępny / *Not available*
Wybór próbki / *Sample selection* ☐ Wybrano – Nr egz./partii: / *Selected – lot/batch No.* ☐ Nie wybrano / *Not selected*

4 Wybór próbki / *Sample selection* ☐ Prawidłowy / *Correct* ☐ Nieprawidłowy / *Incorrect* Wyniki badań / *Result of tests* ☐ Pozytywne / *Positive* ☐ Negatywne / *Negative*

5 Wybór próbki i badania wykazały zgodność z przywołanymi normami/specyfikacjami i badanym typem / *Sample selection and testing demonstrated compliance with the reference standards/specifications and type examined* ☐ Tak / *Yes* ☐ Nie / *No*

CE 1463

Nr jednostki notyfikowanej / *No. of notified body*

Polski Rejestr Statków S.A.
al. Gen. Józefa Hallera 126
80-416 Gdańsk, Poland

tel. (+48) (58) 346 17 00
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e-mail: mailbox@prs.pl
www: http://www.prs.pl

DEKRA Testing and Certification GmbH
Standort Essen
Persönliche Schutzausrüstungen

Adlerstraße 29
45307 Essen, Germany

Tel +49.201.52319-0
Fax +49.201.52319-401
E-Mail CPA@dekra.com

Prüfbericht / *Test report*
No. 3418682.10-CPA

Prüfgegenstand *Testsubject*	Corona SARS-CoV-2 Atemschutzmaske *Corona SARS-CoV-2 respiratory protective mask*
Modell *Type*	RYK MY-002
Hersteller *Manufacturer*	Wenzhou Meiyi Medical Device Co., Ltd. Hengjie Industrial, Xianjiang Street, Ruian Wenzhou, Zhejang, CHINA
Prüfgrundlage *Test requirement*	Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken Rev. 1 vom 26.03.2020 *Testing principle for Corona SARS-CoV-2 pandemic respiratory masks rev. 1 of 2020-03-26*
Prüfergebnis *Test result*	Die Pandemie Atemschutzmaske entspricht der Corona SARS-CoV-2 Prüfanforderungen *The pandemic respiratory protective mask does meet the Corona SARS-CoV-2 test requirements.*
Datum *Date of issue*	22.06.2020

DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart
Zertifizierungsstelle *Certification Body*: Dinnendahlstraße 9, 44809 Bochum
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.com

Veranlassung / *Reason*

Auftragseingang *Date of order*	27/05/2020
Auftraggeber *Applicant*	COL GmbH Dreiherrnsteinplatz 1 63263 Neu-Isenburg
Importeur *Importer*	COL GmbH Dreiherrnsteinplatz 1 63263 Neu-Isenburg
Eingang der Prüfmuster *Date of receipt of test item*	29/05/2020
Prüfzeitraum *Date (s) of performance of tests*	29/05/2020 – 15/06/2020
Prüfstandort *Test location*	DEKRA Testing and Certification GmbH Persönliche Schutzausrüstungen Adlerstraße 29, 45307 Essen, Germany

Zusammenfassung der Prüfung / *Summary of Testing*

Prüfung *Test*		**bestanden** *pass*	**nicht bestanden** *fail*	**nicht anwendbar** *not applicable*
2.2	Sichtprüfung / *Visual inspection*	✔		
2.3	Anlegeprüfung / *Donning test*	✔		
2.4	Durchlass des Filtermediums / *Penetration of the filter medium*	✔		
2.5	Ausatemventil(e) / *Exhalation valve(s)*	✔		
2.6	Atemwiderstand / *Breathing resistance*			
2.6.1	CPA ohne Ventil / *CPA without valve*	✔		
2.6.2	CPA mit Ventil / *CPA with valve*			✔
2.7	Kennzeichnung und Informationen des Herstellers / *Marking and manufacturer's information*	✔		

N/T Nicht getestet oder geprüft / *Not tested or checked*

Bemerkung / *Remarks*:

Die Prüfung gilt als „bestanden", wenn der ermittelte Messwert kleiner oder gleich dem vorgegebenen Grenzwert ist. Mögliche Erklärungen zu „nicht bestandenen" oder nicht durchgeführten Prüfungen können dem Glossar am Ende dieses Prüfberichts entnommen werden.
The test is considered as a "pass" if the measured value is less or equal to the limit.
Possible explanations for "failed" or not performed tests can be found in the glossary at the end of this test report.

DEKRA Testing and Certification GmbH

(Stockmann)
Prüfingenieur/ *Test engineer*

Bewertung der Konformität von Corona SARS-Cov-2 Pandemie Atemschutz (CPA) nach dem Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken Revision 1
Evaluation of the conformity of corona sars-cov-2 pandemic respiratory protection (CPA) according to the testing principle for corona sars-cov-2 pandemic respiratory protection masks revision 1

Berichtsnummer *Report number*	3418682.10-CPA
Prüfgegenstand *Test subject*	Corona SARS-CoV-2 Atemschutzmaske *Corona SARS-CoV-2 respiratory protective mask*
Modell *Type*	RYK MY-002
Hersteller *Manufacturer*	Wenzhou Meiyi Medical Device Co., Ltd. Hengjie Industrial, Xianjiang Street, Ruian Wenzhou, Zhejiang, CHINA
Importeur *Importer*	COL GmbH Dreiherrnsteinplatz 1 63263 Neu-Isenburg

Die Anforderungen des Prüfgrundsatzes sind *The requirements of the test principle are*	✓ Erfüllt *Fulfilled*

Die technische Wirksamkeit des oben genannten Produkts ist im Rahmen der Empfehlung (EU) 2020/403 der Europäischen Kommission vom 13. März 2020 über Konformitätsbewertungs- und Marktüberwachungsverfahren im Kontext der COVID-19 Bedrohung zu vermuten.
The technical efficiency of the above-mentioned product is to be presumed within the framework of the European Commission Recommendation (EU) 2020/403 of 13th March 2020 on conformity assessments and market surveillance procedures in the context of the COVID-19 risk.

Der Prüfgrundsatz kann unter der Website der ZLS eingesehen werden.
The test principle can be accessed under the ZLS website.

Diese Bewertung ist gültig vom 24.06.2020 bis 24.06.2021.
This evaluation of conformity is valid from 2020-06-24 until 2021-06-24.

DEKRA Testing and Certification GmbH
Bochum, 2020-06-24

Jörg-Timm Kilisch
Geschäftsführer *Managing Director*

DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart
Zertifizierungsstelle: Dinnendahlstraße 9, 44809 Bochum,
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.com

Fiscal Year 2020
FDA REGISTRATION CERTIFICATE

Certificate No.: JF-FDA-0323-0104

Certificate Holder:
WENZHOU MEIYI MEDICAL DEVICE CO., LTD.

HENGJIE INDUSTRIAL, XIANJIANG STREET, RUIAN

Wenzhou, Zhejiang, 325200, CHINA

has completed the FDA Establishment Registration (as manufacturer , foreign exporter, contract manufacturer) and Device Listing with the US Food & Drug Administration.

Registration Number: N

Owner/Operator Number: 10063965

Device Listing:

Device#	Product Codes	Device Name
D377460	KHA	MASK, SCAVENGING (Disposable face mask)

Registration Expiration Date: 2020-12-31

J&F TECHNOLOGY SERVICES LLC has verified and declares that the above stated facility is registered with the US Food & Drug Administration, Center for Drug Evaluation and Research, Office of Drug Registration and Listing pursuit to the Code of Federal Regulation 21 CFR 207, on the data state above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. J&F TECHNOLOGY SERVICES LLC assumes no liability to any person or entity in connection with the foregoing. J&F TECHNOLOGY SERVICES LLC is a private registration agent and is not affiliated with the US Food and Drug Administration.

J&F TECHNOLOGY SERVICES LLC.

2424 Morris Ave 818 Union

NEW JERSEY 07083

United States

BeFitLab 百帆测试

Test Report

TL-787

Report No.: BT20050901625

Customer Information:

Customer..... : Wenzhou Meiyi Medical Device Co.,Ltd

Address..... : Hengjie Industrial,Xianjiang Street ,Ruian Wenzhou,Zhengjiang,China

Sample Information:

Sample Name.....: 3D FACIAL PROTECTIVE MASK(KN95 MASK)

Sample Specification....: MY-002

Sample Classification...: FFP2

Sample Description.....: Samples in good condition

Sampled Method.....: All parts were received from customer

Receipt Date.....: 2020-05-09

Testing Information:

Test Items.....: Leakage、Penetration of filter material , etc.

Test Reference.....: EN 149：2001+A1: 2009

Test Result.....: Please refer to the following pages

Written by:	Inspected by:	Approved by:
Arzigul	Yanmei Li	Steven Zhu
Date: 2020-05-18	Date: 2020-05-18	Date: 2020-05-18

BEFITLAB TEST TECHNOLOGY SHANGHAI CO., LTD.

Member of International Standards Certification (ISC) Group

QUALITY MANAGEMENT SYSTEM CERTIFICATE

This is to Certify that the QUALITY MANAGEMENT SYSTEM of

Wenzhou Meiyi Medical Device Co.,Ltd.

Registered Address: Hengjie Village, Xianjiang Street, Ruian City, Wenzhou City, Zhejiang Province (within Wenzhou Yunda Shoes Co., Ltd.)

Audit Address: Hengjie Industrial Zone, Xianjiang Street, Ruian City, Wenzhou City, Zhejiang Province

has been assessed by DCI Certification Service
and found to comply with

GB/T 19001-2016 idt ISO9001:2015

for the

Production and sales of personal protective mask (non-medical)

Certificate Number:	**200628**
Unified Social Credit Code:	**91330381MA2HBJX83N**
Initial Certification:	**30 Aug. 2020**
Issue/Reissue Date:	**30 Aug. 2020**
Certificate Expiry:	**30 Aug. 2021**

Certification Manager

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

CNAS 中国认可 国际互认 管理体系 MANAGEMENT SYSTEM CNAS 142-M

Please scan QR code to check the certificate validity and acquire necessary certification public documents.

Recertification Date: 30 Aug. 2023

This certificate is issued by DCI Certification Ltd. The certificate holder shall accept surveillance audit by DCI and the certificate shall be renewed by DCI prior to its expiry date as required. To verify the validity of certificate, please visit: www.dciglobal.com.cn. the certificate information is also available on the CNCA official website: www.cnca.gov.cn.

DCI CERTIFICATION LTD.

4F, Building 26, Lane 2777 East Jinxiu Road, Polit Free Trade Zone, Shanghai, China
Email: info@dciglobal.com.cn

Test Report

Applicant WENZHOU MEIYI MEDICAL DEVICE CO.,LTD
Address HENGJIE INDUSTRIAL,XIANJIANG STREET ,RUIAN WENZHOU,ZHENGJIANG,CHINA

The following sample(s) and sample information was/were submitted and identified by/on the behalf of the client

Sample Name(s)	3D FACIAL PROTECTIVE MASK(KN95 MASK)
Part No.	MY-002
Color	WHITE
Buyer	RYK
Sample Received Date	Apr. 26, 2020
Testing Period	Apr. 26, 2020 to May 6, 2020

Test Requested As specified by client, to screen the 205 substances of very high concern(SVHC) under Regulation (EC) No 1907/2006 of REACH in the submitted sample(s).

Test Method Please refer to the following page(s).

Test Result(s) Please refer to the following page(s).

Summary According to the analytical results, concentrations of 205 SVHC substances are all less than 0.1%(w/w) in the submitted sample(s).

Tested by Sunny Lin Reviewed by Ophelia Wen

Approved by Hill Zheng Date May 6, 2020

Hill Zheng
Technical Manager

No. S352695075

Centre Testing International Group Co.,Ltd.
CTI Building, Xing Dong Community, Xin'an Sub-district, Bao'an District, Shenzhen City, Guangdong Province, P.R. China

CTI 华测检测 CENTRE TESTING INTERNATIONAL

Test Report

Test Result(s)

Batch	No.	Substance Name(s)	CAS No.	EC No.	Concentration (%) 001	Report Limit (%)
-	-	All tested SVHC (See the candidate list)	-	-	N.D.	-

Batch	No.	Substance Name(s)	CAS No.	EC No.	Concentration (%) 002	Report Limit (%)
-	-	All tested SVHC (See the candidate list)	-	-	N.D.	-

Test Method:
Refer to US EPA3052:1996, US EPA 3050B:1996, US EPA3060A:1996, US EPA 3550C:2007, US EPA 3540C:1996, ISO 17353:2004(E), EN 14582:2016 for sample pretreatment.
Analyzed by ICP-OES, UV-Vis, PLM, SEM, IC, HPLC, GC-MS, GC-MS(NCI), GC-FID and LC-MS-MS.

Sample/Part Description

Sample No.	Sample/Part Description	Number of SVHC
001	Mixed test, all parts(Nonmetal)#	205
002	Silver-white metal	71

Hotline:400-6788-333 www.cti-cert.com E-mail:info@cti-cert.com Complaint call:0755-33681700 Complaint E-mail:complaint@