

NB 0370 CE PPE/ MODULE B

LGAJ Technological Center, S.A. (APPLUS)
Campus UAE + Ronda de la Font del Carme s/n 08193
Bellaterra (Barcelona)
T +34 93 567 20 00
www.appluslaboratories.com

Applus⁺



Notified Body No. 0370

CERTIFICADO DE EXAMEN UE DE TIPO EU-TYPE EXAMINATION CERTIFICATE



No. 0370-4932-PPE/B

ITIC02

ORGANISMO NOTIFICADO Nº NOTIFIED BODY NUMBER	0370 - LGAJ TECHNOLOGICAL CENTER (APPLUS)
SOLICITANTE / FABRICANTE APPLICANT / MANUFACTURER	Dongguan Meio Medical Technology Co.,Ltd. Room 901,unit 1,no.3 Hualde Songgang Industrial Zone,Humen Town,Dongguan,Guangdong Province
PLANTA DE PRODUCCIÓN PRODUCTION SITE	Dongguan Meio Medical Technology Co.,Ltd. No.7, Fazhan Road, Mowu village, Dongguan City, Guangdong Province
REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD / APPLICABLE REGULATION TO GIVE CONFORMITY: REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT	
PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD CONFORMITY ASSESSMENT PROCEDURE	Módulo / Module: B EXAMEN UE DE TIPO / EU TYPE EXAMINATION
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) IDENTIFICATION OF THE PPE (TYPE NUMBER)	Ref.: MY-002 Fish-shaped Filtering half mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE	FFP2 NR
NORMAS ARMONIZADAS / HARMONISED STANDARDS	EN 149:2001 + A1:2009 Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. Requisitos, ensayos, marcado. EN 149:2001 + A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking
FECHA DE EMISIÓN / ISSUE DATE	14/12/2020
VALIDEZ HASTA / VALIDITY UNTIL	14/12/2025
El presente certificado se mantendrá vigente durante 5 años siempre que el producto descrito no sea modificado y cumpla los requisitos esenciales de salud y seguridad establecidos en el Reglamento (UE) 2016/425. Para asegurar dicho cumplimiento, este certificado deberá ir acompañado de la documentación correspondiente a la Evaluación de Conformidad con el tipo según módulo C2, D (realizada por un Organismo Notificado, según frecuencia establecida). This certificate will remain valid for 5 years as long as the indicated product is not modified and fulfills the essential requirements of health and safety established in (EU) Regulation 2016/425. To ensure such compliance, this certificate must be accompanied by the documentation corresponding to the Conformity Assessment to type according to C2, D (carried out by a Notified Body according to the established frequency).	

Xavier Ruiz Peña
Managing Director, Product Conformity B.U.



Este documento carece de validez sin su anexo técnico, cuyo número coincide con el del certificado.
This document is not valid without its technical annex, whose number coincides with the number of certificate.

Puede comprobarse la validez de este certificado en nuestra página web / You can check the validity of this certificate on our website:
www.appluslaboratories.com/certified_products

NB 0370 CE PPE/ MODULE B

LBAI Technological Center, S.A. (APPLUS)
Campus UAB - Ronda de la Font del Carme s/n
08193 Bellaterra (Barcelona)
T +34 93 557 70 00
www.appluslaboratories.com

Applus+

Technical Annex Ed. 1
14/12/2020

ANEXO TÉCNICO TECHNICAL ANNEX

0370-4932-PPE/B

I. MODELOS INCLUIDOS EN EL CERTIFICADO

REFERENCES INCLUDED IN THIS CERTIFICATE

MARCA <i>BRAND</i>	MEDISUN
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: MY-002 Fish-shaped Filtering half mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI <i>PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</i>	FFP2 NR
INFORME DE ENSAYO <i>TEST REPORT</i>	PTC20110406301C-EN01V02 issued by Precise Testing & Certification (Guangdong) Co.,Ltd.(PTC).

NB 0370 FFP2 TEST REPORT



中国认可
国际互认
检测
TESTING
CNAS L5772

Test Report

EN 149:2001+A1:2009 protective devices. Filtering half masks to protect against particles. Requirements, testing, marking

Product: Fish-shaped Filtering half mask
Report No.: PTC20110406301C-EN01V01
Client: Dongguan Meio Medical Technology Co.,Ltd
Client Address: Room 901,unit 1,no.3 Huaide Songgang Industrial Zone,Humen Town,Dongguan,Guangdong Province
Manufacturer: Dongguan Meio Medical Technology Co.,Ltd
Manufacturer Address: No.7, Fazhan Road, Mowu village, Dongguan City, Guangdong Province
Contact: Mrs. Abby
Model(s): MY-002
Classification: FFP2 NR
Date of Tests: 2020.11.17~2020.11.24

Signed for and on Behalf of PTC

Prepare by:

Checked by:

Approved by:

Arne

Jue

Tim Mo



This report is issued according to the general clauses in www.ptc-testing.com by PTC. Responsibility, guarantee and law restriction are defined in the general service clauses. The report is only responsible for the submitted sample(s) except as otherwise noted. The report could not be copied without permission.

Precise Testing & Certification (Guangdong) Co., Ltd. (PTC)
Building 1, No. 6, Tongxin Road, Dongcheng Street, Dongguan, Guangdong, China.
Tel: 86-769-38808222 Fax: 86-769-38826111 http://www.ptc-testing.com

NB 0370 FFP2 TEST REPORT



Test Report

Report No.: PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 2 of 15

Summary of assessment

Clause	Assessment
7.3 Visual inspection	NOT TESTED
7.4 Packaging	PASS
7.5 Material	PASS
7.6 Cleaning and disinfecting	N/A
7.7 Practical performance	PASS
7.8 Finish of parts	PASS
7.9.1 Total inward leakage	PASS
7.9.2 Penetration of filter material	PASS
7.10 Compatibility with skin	PASS
7.11 Flammability	PASS
7.12 Carbon dioxide content of the inhalation air	PASS
7.13 Head harness	PASS
7.14 Field of vision	PASS
7.15 Exhalation valve	N/A
7.16 Breathing resistance	PASS
7.17 Clogging	N/A
7.18 Demountable parts	PASS
9 Marking	NOT TESTED

Remark:

PASS: comply with requirement of standard

N/A: not application

NOT TESTED: the clause were not required

This report is issued according to the general clauses in www.ptc-testing.com by PTC. Responsibility, guarantee and law restriction are defined in the general service clauses. The report is only responsible for the submitted sample(s) except as otherwise noted. The report could not be copied without permission.

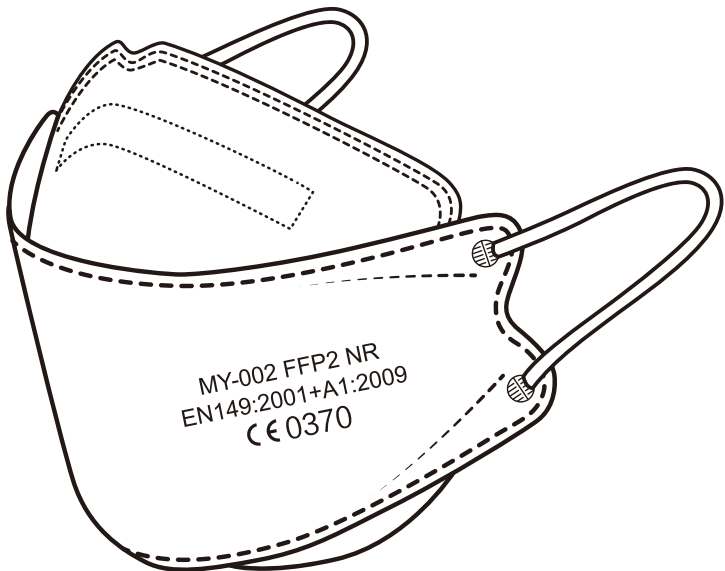
Precise Testing & Certification (Guangdong) Co., Ltd. (PTC)

Building 1, No. 6, Tongxin Road, Dongcheng Street, Dongguan, Guangdong, China.
Tel: 86-769-38808222 Fax: 86-769-38826111 <http://www.ptc-testing.com>

MATERIALS

63%
PP
NONWOVEN

37%
MELTBLOWN
NONWOVEN



MASK PACKAGE(BAG

