

# EU Type Examination Certificate

This is to certify that:

Meditrade GmbH  
Medipark 1, Kiefersfelden  
83088  
Germany

Holds Certificate Number:

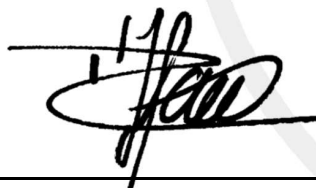
CE 778347

In respect of:

**Respiratory protective devices to EN 149:2001+A1:2009.  
Filtering half masks to protect against particles.**

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified  
Body for the above Regulation  
(Notified Body Number 2797):



Drs. Dave Hagenaaers, Managing Director

First Issued: 2022-10-04

Latest Issue: 2022-10-04

Effective Date: 2022-10-04

Expiry Date: 2027-10-03

Page: 1 of 2



# EU Type Examination Certificate

No. CE 778347

## Product Specification

### Vertical Flat Fold Particulate Half Masks

**Technical specification:** EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles.

Classification – Single shift NR D

**FFP Class:** FFP2

**Model:** **80-806** (Ear loops, without exhalation valve)

## Certificate Administration Details

Products initially approved on BSI Certificate: CE 764011

## Certificate Amendment Record

Issue date	Comments
October 2022	First issue.

### BSI Project Number

2797:22:3754776

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to Type Based on Quality Assurance of the Production Process, Annex VIII (Module D), as referenced on BSI issued Certificate CE 764012.

First Issued: 2022-10-04

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This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request.  
To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated [online](#).

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands  
A member of BSI Group of Companies.



**CE Declaration of Conformity**  
**In accordance with Regulation (EU) 2016/425 of the European**  
**Parliament and of the Council of 09 March 2016 Annex IX**

## **CE Declaration of Conformity No. 154**

### **Personal Protective Equipment**

Respima FFP2 NR D, Filtering half masks, Ear loops, without exhalation valve,  
REF 80-806

### **Name and Address of the Manufacturer**

Meditrade GmbH  
Medipark 1  
83088 Kiefersfelden  
Germany

This declaration of conformity is issued under the sole responsibility of the manufacturer.

### **Object of the Declaration**

The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

- EN ISO 149:2001 + A1:2009
- Regulation (EU) 2016/425

The notified body (BSI 2797) carried out the EU type examination and issued the EU type examination certificate (2797:22:3754776, valid until 03.10.2027). The PPE is subject to the following conformity assessment procedure by the notified body (BSI 2797): Conformity to type based on quality assurance of the production process (module D) according to Annex VIII.

Kiefersfelden, 05.10.2022

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Martin Unterberg  
Regulatory Affairs/ Quality Management

公司: 金士达医疗(咸宁)有限公司  
地址: 湖北省咸宁市咸安区永安东路 79 号  
邮编: 437000  
电话: +86-0715-8912675  
网址: www.kingstarmedical.cn

Name: Kingstar Medical (Xianning) Co., LTD.  
Adresse: Nr. 79 Yong'andong Straße, Xian'an Bezirk 437100,  
Xianning Stadt, Hubei Provinz, Volksrepublik China  
P.C.: 437000  
Tel: +86-0715-8912675  
Website: www.kingstarmedical.cn

## EU-KONFORMITÄTSERKLÄRUNG

### Persönliche Schutzausrüstung:

Marke:	Meditrade
Name:	Filtering half mask
Model:	KSC001
Standard:	EN 149:2001+A1:2009
Klassifikation:	FFP2 NR
Hersteller:	Kingstar Medical (Xianning) Co., LTD.
Hersteller Adresse:	Nr. 79 Yong'andong Straße, Xian'an Bezirk 437100, Xianning Stadt, Hubei Provinz, Volksrepublik China

Diese Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers ausgestellt:

### **Kingstar Medical (Xianning) Co., LTD.**

Der Gegenstand der oben beschriebenen Erklärung steht im Einklang mit den einschlägigen Harmonisierungsrechtsvorschriften der Union: Verordnung (EU) 2016/425 über persönliche Schutzausrüstungen.

Die Erfüllung der in Anhang II aufgeführten einschlägigen Gesundheits- und Sicherheitsanforderungen wurde nachgewiesen.

Die benannte Stelle:

LGAI TECHNOLOGICAL CENTER (APPLUS),  
Campus UAB, Ronda de la Font del Carme s/n, E-08193 Bellaterra (Barcelona), Spain,  
Nummer der benannten Stelle: 0370

hat die EU-Baumusterprüfung (Modul B) durchgeführt und die EU-Baumusterprüfbescheinigung mit der benannten Stelle Nummer 0370 ausgestellt.

Die PSA unterliegt dem in der Verordnung (EU) 2016/425 festgelegten Verfahren zur Bewertung der Konformität mit der Bauart auf der Grundlage einer internen Fertigungskontrolle mit überwachten Produktprüfungen in unregelmäßigen Abständen (Modul C2) unter Aufsicht der benannten Stelle LGAI TECHNOLOGICAL CENTER (APPLUS), NB 0370.

Nummer des PSA-Zertifikats des Moduls B Zertifikat Nr.: 0370-5547-PPE/B

Unterzeichnet für und im Namen von: JianSen Yin

Datum: Nov. 09, 2021



公司: 金士达医疗(咸宁)有限公司  
地址: 湖北省咸宁市咸安区永安东路 79 号  
邮编: 437000  
电话: +86-0715-8912675  
网址: www.kingstarmedical.cn

**Name:** Kingstar Medical (Xianning) Co., LTD.  
**Address:** No. 79 Yong'andong Road, Xian'an District 437100,  
Xianning City, Hubei Province People's Republic of China  
**P.C.:** 437000  
**Tel:** +86-0715-8912675  
**Website:** www.kingstarmedical.cn

## EU DECLARATION OF CONFORMITY

### Personal Protective Equipment:

Brand:	Meditrade
Name:	Filtering half mask
Model:	KSC001
Standard:	EN 149:2001+A1:2009
Class:	FFP2 NR
Manufacturer:	Kingstar Medical (Xianning) Co., LTD.
Manufacturer Address:	No. 79 Yong'andong Road, Xian'an District 437100, Xianning City, Hubei Province, People's Republic of China

This declaration of conformity is issued under the sole responsibility of the manufacturer:

### **Kingstar Medical (Xianning) Co., LTD.**

The object of the declaration described above is in conformity with the relevant Union harmonization legislation: Personal Protective Equipment Regulation (EU) 2016/425.

The fulfillment of the relevant health and safety requirements set out in Annex II has been demonstrated.

The notify body:

LGAI TECHNOLOGICAL CENTER (APPLUS),  
Campus UAB, Ronda de la Font del Carme s/n, E-08193 Bellaterra (Barcelona), Spain,  
Notified Body Number:0370

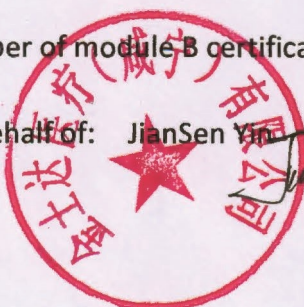
performed the EU type-examination (Module B) and issued the EU type-examination certificate with notified body number 0370.

The PPE is subject to the conformity to type assessment procedure based on internal production control plus supervised product checks at random intervals (Module C2) set out in the Regulation (EU) 2016/425, under surveillance of the notified body LGAI TECHNOLOGICAL CENTER (APPLUS), NB 0370.

PPE certificate number of module B certificate No.: 0370-5547-PPE/B

Signed for and on behalf of: JianSen Yin

Date: Nov. 05, 2021



*Jian Sen Yin* Nov. 05, 2021



Notified Body No. 0370

# CERTIFICADO DE EXAMEN UE DE TIPO

## EU-TYPE EXAMINATION CERTIFICATE

No. **0370-5547-PPE/B**

<b>ORGANISMO NOTIFICADO Nº</b> <i>NOTIFIED BODY NUMBER</i>	<b>0370 - LGAI TECHNOLOGICAL CENTER (APPLUS)</b>
<b>SOLICITANTE / FABRICANTE</b> <i>APPLICANT / MANUFACTURER</i>	<b>Kingstar Medical (Xianning) Co., LTD.</b> No. 79 Yong'andong Road, Xian'an District 437100, Xianning City, Hubei Province, People's Republic of China
<b>PLANTA DE PRODUCCIÓN</b> <i>PRODUCTION SITE</i>	<b>Kingstar Medical (Xianning) Co., LTD.</b> No. 79 Yong'andong Road, Xian'an District 437100, Xianning City, Hubei Province, People's Republic of China
<b>REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD   APPLICABLE REGULATION TO GIVE CONFORMITY:</b> <b>REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL</b> <i>REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT</i>	
<b>PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD</b> <i>CONFORMITY ASSESSMENT PROCEDURE</i>	Módulo // <i>Module:</i> <b>B</b> <b>EXAMEN UE DE TIPO   EU TYPE EXAMINATION</b>
<b>IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)</b> <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: KSC001 Filtering half mask
<b>NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI   PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</b>	FFP2 NR
<b>NORMAS ARMONIZADAS   HARMONISED STANDARDS</b>	EN 149:2001 + A1:2009 Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. Requisitos, ensayos, marcado. <i>EN 149:2001 + A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking</i>
<b>FECHA DE EMISIÓN   ISSUE DATE</b>	<b>08/04/2021</b>
<b>VALIDEZ HASTA   VALIDITY UNTIL</b>	<b>08/04/2026</b>
<p>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).</p> <p><i>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).</i></p>	



  
LGAI Technological Center, S.A.  
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](http://www.appluslaboratories.com/certified_products)

**ANEXO TÉCNICO**  
*TECHNICAL ANNEX*

**0370-5547-PPE/B**

**I. MODELOS INCLUIDOS EN EL CERTIFICADO**

*REFERENCES INCLUDED IN THIS CERTIFICATE*

<b>MARCA</b> <i>BRAND</i>	POMPOM LIFE
<b>IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)</b> <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: KSC001 Filtering half mask
<b>NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI</b> <i>PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</i>	FFP2 NR
<b>DESCRIPCIÓN</b> <i>DESCRIPTION</i>	MEDIA MÁSCARA FILTRANTE SIN VÁLVULA, DE TIPO PLEGABLE VERTICAL, DE 5 CAPAS, DE COLOR BLANCO, CON LAZOS DE OREJA Y CLIP NASAL INTERIOR. TAMAÑO: 105mm*155mm. // VALVELESS FILTERING HALF MASK, VERTICAL FOLDING TYPE, 5 LAYERS, WHITE COLOUR, WITH EARLOOPS AND INTERIOR NOSE CLIP. SIZE: 105mm×155mm
<b>INFORME DE ENSAYO</b> <i>TEST REPORT</i>	PTC21012500501C-EN01V01 issued by Precise Testing & Certification (Guangdong) Co.,Ltd.(PTC).