

EU TYPE-EXAMINATION CERTIFICATE

n. EC: 21-0031Rev.1

In realisation of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9th of March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

DOLOMITICERT SCARL

authorised by the Ministry of Economic Development and by the Ministry
of Labour and Social Policies with the decree issued in date 11th March 2021
NOTIFIED BODY IDENTIFICATION NUMBER: 2008

considered the application for EU type-examination no. 210125, presented in date 21/04/2021

CERTIFIES THAT

the following personal protective equipment model

Respiratory protective devices - Filtering half mask to protect against particles

KZ-06

presented by

Collextion Medical Division S.P.A.

Via Theodore Roosevelt 27 - 81100 Caserta - Italy

results to be in conformity with the applicable essential requirements included into Annex II of the Regulation (EU) 2016/425 dated 9th of March 2016.

The description of the personal protective equipment model, the normative reference, the verification results and the description of the CE marking on the equipment are described on page 2. 3 .4 of the present document.

First issue date: 26/02/2021

Renewal or revision date: 23/04/2021

Expiration date: 25/02/2026

Longarone, 23/04/2021

The Director of the Notified Body


(Tommaso Morandin)

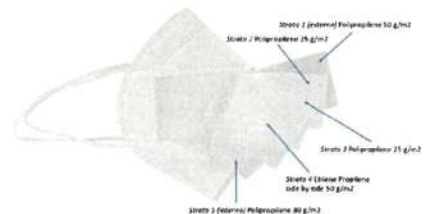


This document consists of no. 4 numbered pages.

1. Description of the Personal Protective Equipment

Product Designation: KZ-06
 Commercial Trade: CMD SPA
 Product Description: Respiratory protective devices - Filtering half mask to protect against particles
 Intended purpose: Filtering half mask to protect against particles except for escape purposes.
 Model: KZ-06
 Reference code: /
 In Compliance with Standard(s): EN 149:2001 + A1:2009 and /
 PPE Category: III
 Mask designation: FFP2 NR
 Size(s): One size
 Weight (g): Approximately 5 grams
 Main materials: Face blank: Polypropylene 50g/m2 (1st and external layer); Polypropylene 25g/m2 (2nd layer); Polypropylene 25g/m2 (3rd layer); Ethylene-propylene Side by side (ES) 50g/m2 (4th layer); Polypropylene 30g/m2 (5th and internal layer). Nose clip: Polyethylene coated iron wire. Elastic ear loops: Spandex ribbon in polyester brocade.
 Main dimensions: Face blank (Length x Height): 100 x 165 mm. Nose clip (Length x Height): 80 x 7 mm. Elastic ear loops (Length x Width): 220 x 5 mm.
 Variants: The particle filtering halfmask model "KZ-06" is produced in two color versions: White (code "KZ-06") and Black (code "KZ-06-Black").
 Manufacturer's name: Collexion Medical Division S.P.A.
 Manufacturer's address: Via Theodore Roosevelt 27 - 81100 Caserta - Italy
 Authorised Representative's name: /
 Authorised Representative's address: /
 Certificate holder : Collexion Medical Division S.P.A.
 Holder's address: Via Theodore Roosevelt 27 - 81100 Caserta - Italy

CMD SpA
 KZ-06 FFP2 NR
 EN 149:2001 + A1:2009
 >5mm  2008



Componente	Composizione del materiale	Peso (g/m2)	Fornitore
Corpo della mascherina	Strato 1 (esterno)	50	Zhejiang Top Mask Technology Co., LTD
	Strato 2	25	Zhejiang Zhongshan New Material Co., LTD
	Strato 3	50	Zhejiang Zhongshan New Material Co., LTD
	Strato 4	50	Zhejiang Juyao Newchem Co., LTD
	Strato 5 (interno)	30	Zhejiang Juyao Newchem Co., LTD

Componente	Composizione	2. Fornitore
Clip naso	Filo metallico rivestito in polietilene	Zhejiang Zhongshan New Material Co., LTD
Elastico orecchie	Nastro spandex in broccato poliestere	Zhejiang Zhongshan New Material Co., LTD



2. Levels of protection offered by the personal protective equipment and notes:

Applicable Standards:

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

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/

The protection equipment KZ-06

is compliant with the basic requirements provided by the standard(s) of reference for the particular fields of utilization the device is addressed to.

EN 149:2001 + A1:2009 and /

Characteristics of the protection equipment are:

Particle filtering half mask FFP2 NR

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/

/

PPE description and notes:

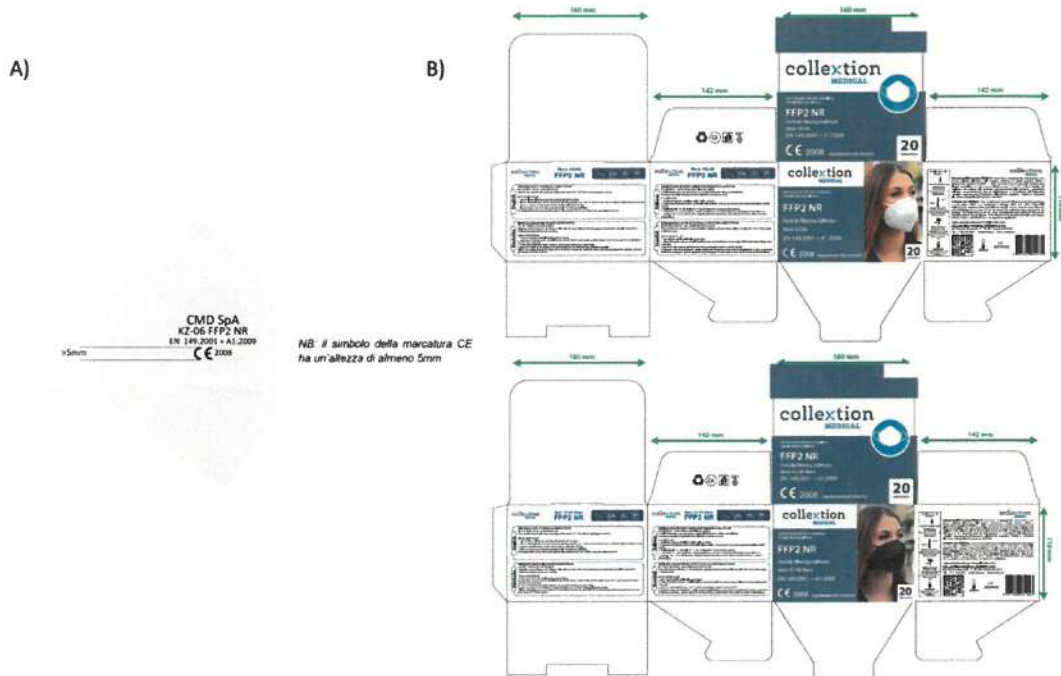
Valveless and disposable filtering half mask classified as FFP2 NR according to its filtering efficiency and its maximum total inward leakage. Filtering half masks are intended to provide adequate sealing on the face of the wearer against the ambient atmosphere when the skin is dry or moist and when the head is moved. This type of device covers the nose, the mouth and the chin of the user and consists entirely or substantially of filter material or comprises a facepiece in which the main filter(s) form an inseparable part of the device. Particle filtering half mask are designed to protect against both solid and liquid aerosols. This EU Type-Examination Certificate is the first revision of the previous one issued by Dolomitcert Scarl on 26/02/2021 with number EC 21-0031. This revision considers the inclusion of the color variant KZ-06-Black.

3. Test results and test examinations are covered by the following test reports:

Dolomitcert Scarl	210245	25/02/2021
SGS-CSTC Standard Technical Services (Shanghai) Co., Ltd Testing Center	SL52035272757801TX	28/07/2020
Certottica Scarl	211720	08/04/2021
/	/	/
/	/	/



4. Marking



Placement of the marking: Picture A: Marking on the Particle filtering half mask (dimensions in mm)
 Picture B: Marking on the packaging (dimensions in mm)

5. Declaration for category III personal protective equipment

For category III PPE, this EU Type-Examination Certificate shall be used only in combination with one of the evaluation procedures in accordance with Article 19, letter c), of the Regulation (EU) 2016/425

Applicability for the product covered by this EU Type-Examination Certificate:

YES

Terms and conditions under which the Certificate is issued

- Marking and instructions were examined in **Italian**. Language versions other than the one specified above are under the complete responsibility of the Manufacturer or of his Authorised Representative.
- Any variation to the product, to the technical file or, in the provided cases, to the manual or to the quality control procedures, shall be notified in time to DOLOMITICERT.
- The Manufacturer or his Authorised Representative shall respect the procedures and the regulations provided by DOLOMITICERT for the EU Certification.
- Copies of this Certificate, supplied to third parties, shall be reproduced in their entirety.
- The present Certificate shall be carefully kept by the Manufacturer to be shown, on request, to the Organism of control or to the Vigilance Administration.
- The present Certificate remains property of DOLOMITICERT, which can ask for it back if some of the above mentioned conditions are not respected.
- Any subsequent revision of the present document automatically deletes and replaces it.
- The present document can include only a limited description of the product under certification; for a more detailed description, please refer to the correspondent Technical Documentation.