

Dichiarazione di conformità UE

COLLEXTION MEDICAL DIVISION S.P.A.

Via Theodore Roosevelt 27
81100 Caserta
Italia

La conformità UE è certificata dall'Organismo Notificato DOLOMITICERT S.C.A.R.L. (Z.I. Villanova 32013 - Longarone (BL) - Italia - Notified Body number: 2008) che ha rilasciato il Certificato CE del Tipo N. 21-0154 Rev.01 e che sottopone il dispositivo alla procedura di controllo prevista all'allegato VII (modulo C2).

La COLLEXTION MEDICAL DIVISION SPA dichiara, sotto la propria esclusiva responsabilità, che il dispositivo di protezione individuale

AB03 e la sua variante AB03-BLACK

è conforme ai requisiti essenziali di salute e sicurezza previsti all'Allegato II del Regolamento (UE) 2016/425 del Parlamento Europeo e del Consiglio del 9 marzo 2016 sui dispositivi di protezione individuale e che abroga la direttiva 89/686/CEE del Consiglio.

Il dispositivo è una semimaschera filtrante antipolvere di tipo FFP2 classificato categoria III, secondo quanto previsto all'Allegato I del Regolamento (UE) 2016/425.

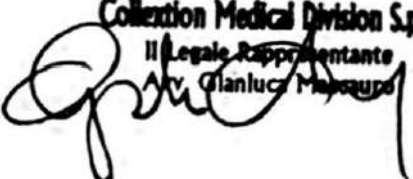
Conformemente all'art.19 del Regolamento (UE) 2016/425, le procedure seguite per la valutazione della conformità UE per il dispositivo AB03 di Categoria III sono quelle di ESAME UE DEL TIPO (modulo B) di cui all'allegato V e di CONFORMITÀ AL TIPO BASATA SUL CONTROLLO INTERNO DELLA PRODUZIONE UNITO A PROVE DEL PRODOTTO SOTTO CONTROLLO UFFICIALE EFFETTUATE A INTERVALLI CASUALI (modulo C2) di cui all'allegato VII.

Il dispositivo AB03 e la sua variante AB03-BLACK rispetta inoltre le seguenti norme tecniche e standard applicabili: -EN 149:2001+A1:2009 - Dispositivi di protezione delle vie respiratorie-Semimaschere filtranti antipolvere -Requisiti, prove, marcatura

Caserta, 14/01/2022

Il legale rappresentante Avv. Gianluca Maccauro
COLLEXTION MEDICAL DIVISION S.P.A

Collection Medical Division S.p.A.
Il Legale Rappresentante
Avv. Gianluca Maccauro



EU TYPE-EXAMINATION CERTIFICATE

n. EC: 21-0154Rev.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. 210331, presented in date 23/12/2021

CERTIFIES THAT

the following personal protective equipment model

Respiratory protective devices - Filtering half mask to protect against particles

AB03

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.

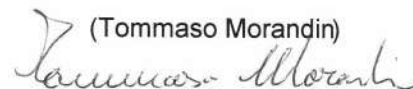
First issue date: 06/08/2021

Renewal or revision date: 13/01/2022

Expiration date: 05/08/2026

Longarone, 13/01/2022

The Director of the Notified Body

(Tommaso Morandin)


This document consists of no. 4 numbered pages.

1. Description of the Personal Protective Equipment

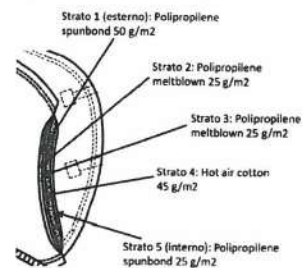
Product Designation: AB03
 Commercial Trade: CMD SPA
 Product Description: Respiratory protective devices - Filtering half mask to protect against particles
 Intended purpose: Filtering half mask to protect against particles except for escape purposes.

Model: AB03
 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: White or colored spunbond polypropylene 50g/m2 (1st and external layer); White meltblown polypropylene 25g/m2 (2nd layer); White meltblown polypropylene 25g/m2 (3rd layer); White hot air cotton 45g/m2 (4th layer), White or colored spunbond polypropylene 25g/m2 (5th and internal layer). Nose clip: Polyethylene and mild steel. Elastic ear loops: Polyester.

Main dimensions: Face blank (Height x Width): Approximately 160±5 x 107±5 mm. Nose clip (Length x Width): Approximately 96±5 x 5±2 mm. Elastic ear loops (Length x Width): Approximately 165±5 x 5±2 mm.

Variants: The particle filtering halfmask model "AB03" is produced in the 2-point weld variant in the following color versions: White (code "AB03/2P") and Black (code "AB03/2P-Black"). The model "AB03" is also produced in the 3-point weld variant in the following color versions: White (code "AB03/3P") and Black (code "AB03/3P-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



Componente	Composizione del materiale	Peso (g/m2)
Strato 1 (esterno)	Polipropilene spunbond bianco o nero	50
Corpo della maschera	Strato 2	Meltblown in polipropilene bianco
	Strato 3	Meltblown in polipropilene bianco
Strato 4	Hot air cotton bianco	45
Strato 5 (interno)	Polipropilene spunbond bianco o nero	25

Componente	Composizione
Clip naso	Acciaio dolce + polietilene
Elastica orecchie	Poliesteri

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"

/

/

The protection equipment AB03

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

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 masks are designed to protect against both solid and liquid aerosols. The head harness of the device is represented by two nuchal elastic bands. This EU Type-Examination Certificate is the first revision of the previous one issued by Dolomitcert Scarl on 06/08/2021 with number EC 21-0154. This revision considers the inclusion of the two-welding point variant with ink marking and the three-welding point variant with roller marking and corresponding colours. The revision also includes the inclusion of the 2-piece polybag.

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

Dolomitcert Scarl	09/12/2021	211803
Dolomitcert Scarl	23/09/2021	211383
Dolomitcert Scarl	26/07/2021	211172
Dolomitcert Scarl	14/04/2021	210261
ICS Laboratories, Inc	02/04/2021	T15803-01-1
Certottica Scrl	30/04/2021	212404
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4. Marking

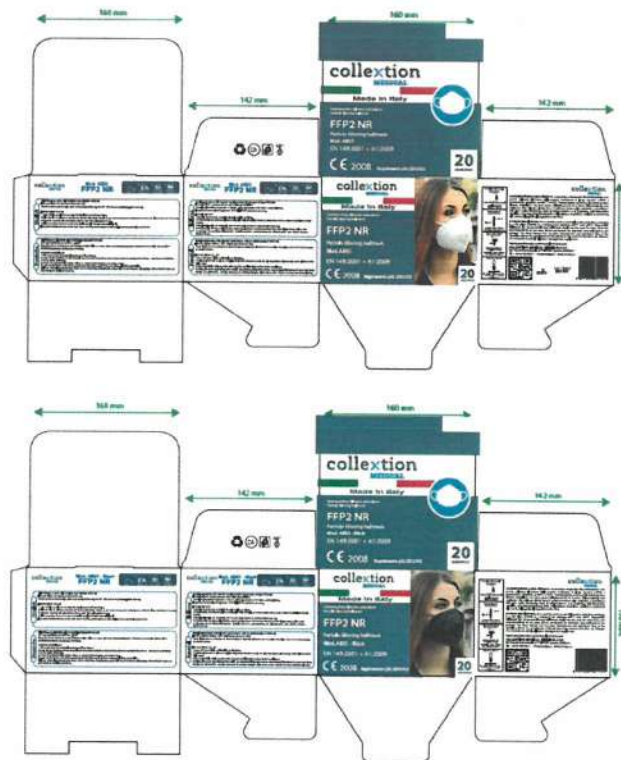
A)

Ink marking

CMD S.p.A.
 FFP2 NR Mod. AB03
 EN 149:2001 + A1:2009
 Made in Italy



B)



Roller marking

CMD S.p.A.
 Mod. AB03
 FFP2 NR
 EN 149:2001 + A1:2009
 Made in Italy



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

- a) 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.
- b) 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.
- c) The Manufacturer or his Authorised Representative shall respect the procedures and the regulations provided by DOLOMITICERT for the EU Certification.
- d) Copies of this Certificate, supplied to third parties, shall be reproduced in their entirety.
- e) 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.
- f) The present Certificate remains property of DOLOMITICERT, which can ask for it back if some of the above mentioned conditions are not respected.
- g) Any subsequent revision of the present document automatically deletes and replaces it.
- h) 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.

