

EU TYPE-EXAMINATION CERTIFICATE

n. EC: **21-0095Rev.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. **230042** , presented in date **09/02/2023**

CERTIFIES THAT

the following personal protective equipment model

Respiratory protective devices - Filtering half mask to protect against particles

MSK004

presented by

Ramedical Srl

Via Regina Elena, 32 - 35010 Grantorto (PD) - 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: **21/05/2021**

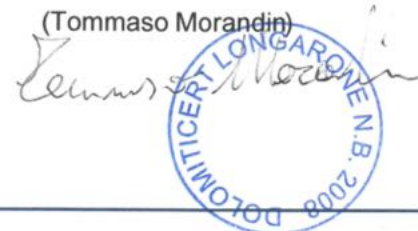
Renewal or revision date: **10/02/2023**

Expiration date: **20/05/2026**

Longarone, **10/02/2023**

The Director of the Notified Body

(Tommaso Morandin)



This document consists of no. 4 numbered pages.

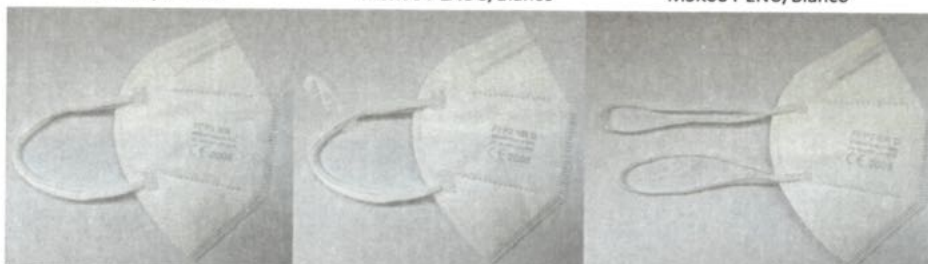
1. Description of the Personal Protective Equipment

Product Designation:	MSK004
Commercial Trade:	Ramedical.
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:	MSK004
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 5,5
Main materials:	Layer 1 (outer): TNT PP Spunbond 50 g/m ² , Layer 2: TNT PP Meltblown 25 g/m ² , Layer 3: TNT PP Meltblown 25 g/m ² , Layer 4: TNT PP Air Cotton 50 g/m ² , Layer 5 (interior): TNT PP Spunbond 25 g/m ² , Nose clip: White polyethylene with double mild steel core of 0.45 mm, Head harness: 5mm tubular elastic cord 86% Nylon braided with 14% elastomer, Nuchal hook: Polyethylene
Main dimensions:	Length: Approximately 106 mm Height: Approximately 160 mm
Variants:	Model with elastic ear loops (FFP2 NR): MSK004/Bianco, MSK004/Grigio, MSK004/Giallo, MSK004/Arancione, MSK004/Rosa, MSK004/Verde, MSK004/Azzurro, MSK004/BLU, MSK004/Nero. Model with nape hook and elastic ear loops (FFP2 NR D): MSK004-EAUG/Bianco, MSK004-EAUG/Grigio, MSK004-EAUG/Giallo, MSK004-EAUG/Arancione, MSK004-EAUG/Rosa, MSK004-EAUG/Verde, MSK004-EAUG/Azzurro, MSK004-EAUG/BLU, MSK004-EAUG/Nero. Model with nape elastic (FFP2 NR D): MSK004-ENU/Bianco, MSK004-ENU/Grigio, MSK004-ENU/Giallo, MSK004-ENU/Arancione, MSK004-ENU/Rosa, MSK004-ENU/Verde, MSK004-ENU/Azzurro, MSK004-ENU/BLU, MSK004-ENU/Nero.
Manufacturer's name:	Ramedical Srl
Manufacturer's address:	Via Regina Elena, 32 - 35010 Grantorto (PD) - Italy
Authorised Representative's name:	/
Authorised Representative's address:	/
Certificate holder :	Ramedical Srl
Holder's address:	Via Regina Elena, 32 - 35010 Grantorto (PD) - Italy

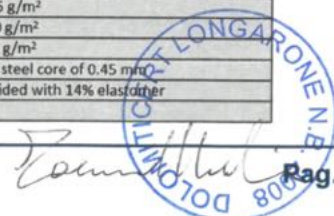
MSK004/Bianco

MSK004-EAUG/Bianco

MSK004-ENU/Bianco



Component	Composition
layer 1 (outer)	TNT PP Spunbond 50 g/m ²
Layer 2	TNT PP Meltblown 25 g/m ²
Layer 3	TNT PP Meltblown 25 g/m ²
Layer 4	TNT PP Air Cotton 50 g/m ²
Layer 5 (interior)	TNT PP Spunbond 25 g/m ²
Nose clip	White polyethylene with double mild steel core of 0.45 mm
Head harness	5mm tubular elastic cord 86% Nylon braided with 14% elastomer
Hook	Polyethylene



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 MSK004

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:

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. This EU Type-Examination Certificate is also the first revision of the one issued by Dolomiticert Scarl on 21/05/2021 with number EC 21-0095. This revision considers the inclusion of new variants: one with a nuchal elastic in all the colours available in the first issue and the other with a nuchal hook and ear loops in all the colours available in the first issue. The new variants will also comply with the clogging requirement.

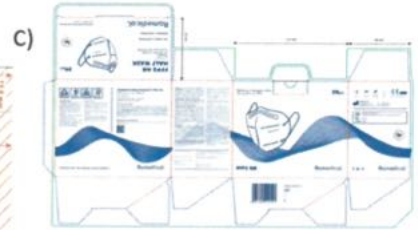
3. Test results and test examinations are covered by the following test reports:

Dolomiticert Scarl	09/02/2023	230135
Dolomiticert Scarl	09/02/2023	230134
Dolomiticert Scarl	17/05/2021	210440
Certottica Scarl	12/07/2021	214231
Certottica Scarl	05/05/2021	212202
Certottica Scarl	05/05/2021	212201
Certottica Scarl	20/04/2021	211852
ICS inc. Laboratories	03/05/2021	T15880-01-1 Issue 1
/	/	/
/	/	/
/	/	/
/	/	/
/	/	/
/	/	/
/	/	/
/	/	/
/	/	/

4. Marking

A) **FFP2 NR**
 MSK004 Made in Italy
 EN 149:2001 + A1:2009
 > 5 mm **CE 2008**

FFP2 NR D
 MSK004 Made in Italy
 EN 149:2001 + A1:2009
 > 5 mm **CE 2008**



Placement of the marking:

- A) Marking on the Particle filtering half Mask
- B) Marking on packaging represented by the polybag (Only for variants with ear loops)
- C) Marking on packaging represented by the box (20 units) (Only for variants with ear loops)
- D) Marking on packaging represented by the box (20 units) (Only for variants with nuchal hook)
- E) Marking on packaging represented by the box (20 units) (Only for variants with nuchal elastics)
- F) Marking on packaging represented by the box (10 units) (Only for variant with ear loops)

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.