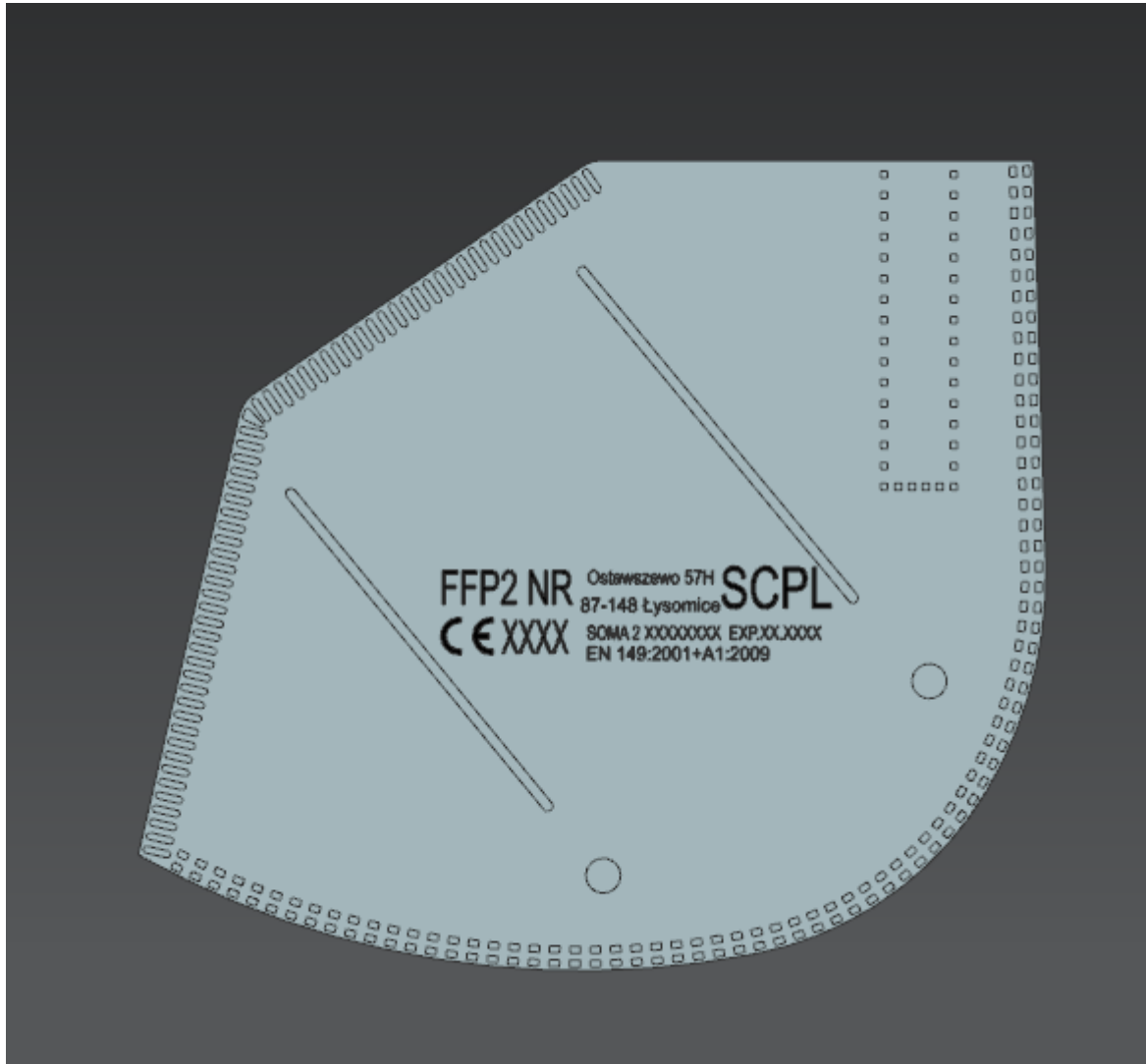


Complete description of the PPE and of its intended use

Marking:



Description:

SCPL – symbol used to identify the manufacturer of the half-mask

SOMA2 - code of the product

EN 149:2001+A1-2009 - the reference standard number and the year of its publication

FFP2 - symbol of the protection class

NR - This respirator is limited to single shift use only

XXXX - Number of the Notified body involved in the Conformity Assessment and Supervised body

XXXXXXXX – Batch number same as date of production

EXP.MM.RRRR – Expiry date: printed on the product

CE marking - indicates conformity with the Regulation (EU)

Expiration date:

- It is recommended to use the product within 36 months from the date of production.
- The expiry date is marked as (EXP. XX.XXXX → MM/YYYY)

a. An assessment of the risks against which the filtering half- mask SOMA 2 is intended to protect

Filtering half- mask Soma 2 protects against solid particles and/or liquid particles forming aerosols up to 10 x NDS according to EN 149:2001+A1:2009 for protection class FFP2.

Contraindications and risks of improper use:

- The use of half-masks in poorly ventilated or small spaces where oxygen deficiency occurs or may occur (concentration below 17%) - risk of hypoxia and nausea.
- Facial hair and scars may reduce effectiveness of the half mask such as adhesion - risk of lack of protection.
- Using a half-mask in an atmosphere where the type, concentration and properties of harmful substances are not known - risk of lack of protection.
- The half mask does not protect against contamination in the form of vapors and gases.
- Using damaged or past the expiry date half masks or longer than 8 hours - risk of lack of protection.
- Transport or storage in inappropriate conditions - risk of losing protective properties.
- Using a half mask in inappropriate conditions and not following the rules of its use - risk of poisoning.
- Failure to follow instructions and information on the use may reduce effectiveness of the respirators-risk of lack of protection.
- Modification of half- mask or its components- the risk of lack of protection.
- Using disposable half- masks marked with letters "NR" for more than one working shift (8 hors)- the risk of lack of protection.
- Using the half-mask in an atmosphere containing aerosol particles in a concentration exceeding the range of individual protection classes according to the table below.

PROTECTION CLASS	APPLICATION RANGE - NDS*
FPP1-filtration ≥80%	4
FPP2-filtration ≥94%	10
FPP3-filtration ≥99%	30

*NDS - Maximum Allowable Concentration

b. A list of the essential health and safety requirements that are applicable to the PPE

The filtering half mask SOMA 2 meets the requirements of REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

Intended use

Filtering half- mask Soma 2 is a respiratory protective equipment and is intended to protect the user against solid particles and/or liquid particles forming aerosols up to 10 x NDS according to EN 149:2001+A1:2009 of protection class FFP2.

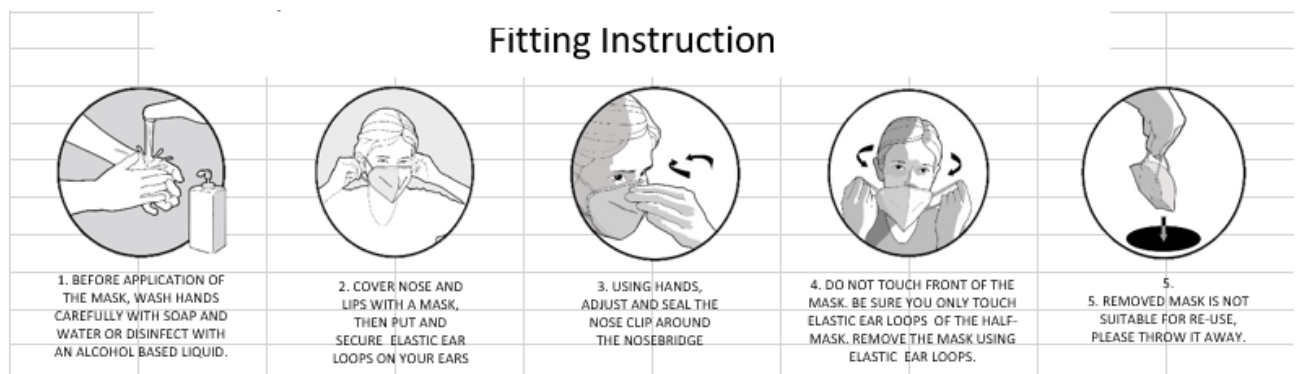
Air flows during exhalation and inhalation phases of breathing cycle through the filtration layer. Half-mask must fit tight the face, facial hair may have negative impact on half- mask seal to face.

Filtering half- mask Soma 2 is a disposable protective equipment – for a maximum of a single shift use .

Before each use of the half mask, check the expiry date, the condition of the half-mask and its packaging for any visible damage, dirt and any missing components. A half mask that is damaged or which shelf life has been exceeded is not suitable for use.

Before each use, read the manual carefully. The user must be acquainted with instructions and the purpose of the equipment. Before using the half-mask, the type and concentration of aerosol in the air in the place where the mask is used must be known.

Fitting instruction for filtering half-mask SOMA2:



c. References of harmonised standards used

List of harmonised standards used:

- EN 149:2001+A1:2009 - Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking.
- Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

Half- mask are considered to be compliant with requirements when:

- Breathing resistance flow rate : 30l/min ≤ 60 Pa, 95l/min ≤ 240 Pa, 160l/min ≤ 300 Pa
- Filtration over 95%