

Translation of the original user's manual

Introduction

EN

Dear customer,
Thank you for the confidence you have shown in the Extol® brand by purchasing this product. This product has been tested for reliability, safety and quality according to the prescribed norms and regulations of the European Union.

Contact our customer and consulting centre for any questions at:

www.extol.eu service@madalbal.cz

Manufacturer: Madal Bal a. s., Prům. zóna Příluky 244, 76001 Zlín, Czech Republic

Date of issue: 1. 10. 2020

TECHNICAL SPECIFICATIONS OF RESPIRATORS

Model/ designation of the respirator	Class of filter			NR	Layer of active carbon	Exhalation valve	Type
	FFP1	FFP2	FFP3				
8856714	•			•			Formed
8856715	•			•		•	Formed
8856716	•			•		•	Folding
8856723		•		•			Formed
8856724		•		•			Formed
8856727		•		•	•		Folding
8856728		•		•	•	•	Folding
8856734		•	•	•		•	Formed
8856738		•	•	•	•	•	Formed

Table 1

Explanations for table 1:

The symbol "•" means YES; absence of the symbol in the table means NO.

The filter class (efficiency) FFP1, FFP2, FFP3: filter filtration efficiency classification according to the harmonised norm EN 149 with further specifications provided in table 2.

NR: Respirator intended for single disposable use (it cannot be cleaned for repeat use).

Layer of active carbon: Respirators with a layer of active carbon are suitable for cases where unpleasant non-toxic odours are present, or for the occurrence of ozone from road traffic, smog and furthermore in cases recommended according to table 2.

Exhalation valve: This is a one-way flap that closes upon inhalation, i.e. inhaled air is filtered through the material of the respirator, and opens upon exhalation. The exhalation valve extracts exhaled air out of the respirator, which increases comfort when the respirator is used, since it reduces the heating of the wearer's face, particularly in higher ambient temperatures or during physically demanding work, which increases the breathing frequency.

In order to reduce the risk of infecting other persons an infectious person must always use a respirator model without an exhalation valve, since in the case of respirators with an exhalation valve the exhaled air is not filtered by the material of the respirator.

Formed/folding type:

The formed type of respirator has a permanent form (body) and increases the comfort of the user during more demanding work, where the respirator retains its shape during intensive inhalation or when worn in windy weather.

The folding type of respirator has a soft form and thanks to this can be folded for easier carrying, e.g. in the pocket of clothing or in a handbag.

Material of the respirator: polypropylene (PP)

USING THE RESPIRATOR ACCORDING TO THE FILTRATION EFFICIENCY

CLASS FFP1, FFP2 AND FFP3

Respirators are intended for protection against the inhalation of solid particulates and aerosols based on the filtration efficiency class FFP1, FFP2 and FFP3, the national assigned protection factor APF and permitted exposure limits for given harmful substances (see below). Classification of filtration classes FFP1, FFP2 and FFP3 according to efficiency is given by the harmonised norm EN 149.

Filter class (efficiency) – use according to NPK-P/PEL	Example of material particulate types
<p>FFP1</p> <p>Filtration efficiency of respirator material min. 80 %</p> <p>Total penetration through respirator: max. 22 %</p> <p>Against non-toxic dust and aerosols up to a concentration of 4 times the permitted exposure limit (PEL) for the given harmful substance.</p>	<p>Cement²⁾, limestone, cinder, cereal grain dust, dust from abrasives, plaster²⁾</p>
<p>FFP2</p> <p>Filtration efficiency of respirator material min. 94 %</p> <p>Total penetration through respirator: max. 8 %</p> <p>Against dust with predominantly irritating effects and aerosols up to a concentration of 10 times the permitted exposure limit (PEL) for the given harmful substance.</p>	<ul style="list-style-type: none"> Cotton, flax, hemp, silk, synthetic textile fibres, (textile industry) Feathers, animal fur, pollen, mites (allergens) Flour, tobacco, tea, coffee, spices, dust from dried herbs (food processing) Fibreglass, glass, resin, concrete, plaster, soft wood, old paint coats, rust (grinding building materials) Smog and ground-level ozone from road traffic (environment) + layer of active carbon Unpleasant non-toxic odours + layer of active carbon Attic dust, soot (cleaning – soiled with standard dust) Coal, stone (mining activity)

FFP3

Filtration efficiency of respirator material min. 99 %

Total penetration through respirator: max. 2 %

Against toxic particulates, viruses, spores, bacteria, radio active dust up to a concentration of 30 times the permitted exposure limit (PEL) for the given harmful substance.

- Viruses³⁾, bacteria, mould spores (harmful biological agents)
- Machining hard wood (e.g. oak, beech)
- Mineral and glass insulating wool
- Welding of stainless steel, aluminium
- Welding of steel, zinc
- Welding fumes + layer of active carbon
- Handling of asbestos and lead

ATTENTION

An infectious person must have a respirator model without the exhalation valve since exhaled air exits through the exhalation valve without filtration by the material of the respirator.

ATTENTION

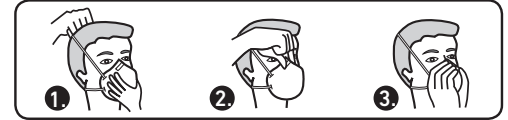
For protection against damaging biological agents, it is necessary to concurrently use gas-tight glasses, which prevent ingress of biological agents into eyes.

- The respirator must be replaced when dust penetrates through the respirator and soiling, odour or other evidence of penetration of harmful substances through the respirator is identified on the inside of the respirator; furthermore also when it is damaged or breathing resistance increases significantly making breathing difficult.
- The respirator is not intended to be cleaned and disinfected for repeat use.
- The respirator is not intended for use in an environment with an explosion hazard.
- Tight seal requirements will most probably not be met if the user has whiskers on the contact surface of the sealing line of the respirator.
- The respirator should not be used by persons whose whiskers, facial shape or scars prevent proper tight contact of the respirator with the face.
- Not following the instructions and warnings may reduce the efficiency of the respirator and may result in damage to health.

PROCEDURE FOR FITTING THE RESPIRATOR ON THE FACE:

ATTENTION

- To ensure that the respirator provides protection; it is necessary to fit it correctly on the face because an incorrectly fitted or located respirator will significantly reduce the level of protection!
- Tight seal requirements will not be met if the user has whiskers or hair on the contact surface of the sealing line. Prior to fitting the respirator, check that it is complete and that it has not been damaged mechanically. Do not use respirators that have been used for longer than one work shift, respirators with increased breathing resistance and dogging, or that are past the expiry date shown on the packaging of the respirator.



- Position the top and bottom fastening rubber bands into the positions according to fig. 1, so that the top and bottom parts of the respirator are seated as tightly as possible in contact with the face.
- With your fingers, thoroughly squeeze the nose strip against the nose and form it along the contour of the nose so that the respirator holds as best as possible on the face and seals along the contact line (fig. 2).
- Check the respirator for leaks along the contact lines with the face by forcefully and intensively breathing in. If the respirator is not sealing and air is passing around the nose or elsewhere along the sealing line, it is necessary to readjust the respirator by moving it to a more suitable position, changing the shape of the nose strip or moving the fastening rubber bands to a more suitable position, see fig. 3.

ATTENTION

In the event of increased breathing resistance, replace the respirator for a new one.

STORAGE

- The respirator must be stored in an environment with a temperature of +5° to +38°C at a relative humidity of < 70%.
- The lifetime (expiry date) is provided on the sales packaging (see respective pictogram in table 4) under the condition that the specified storage conditions are adhered to.

MEANINGS OF MARKINGS ON THE RESPIRATOR AND SMALLEST SALES PACKAGING

	Manufacturer's trade mark. The address of the manufacturer is provided on the product in the form: Made by Madal Bal a.s., Prům. zóna Příluky 244, CZ-76001 Zlín
EN 149:2001 + A1:2009	Harmonisation norm defining the requirements for filtration half face masks for protection against particulates; norm's year of issue.
	It meets all the respective provisions of the harmonisation legal regulation for personal protective equipment (EU) 2016/425.
	Number of the notified entity that performed the EU assessment of the filtration half face mask type tested according to EN 149+A1:2009 and that performs supervision of production according module D.
FFPX NR	"FFP" - "Filtering Facepiece Particles" - "Face filtration mask against solid particulates". "X" - filter class 1; 2 or 3 according to filtration efficiency. "NR" - designed for use for the duration of a single shift only, then the respirator must be disposed of.
	Final lifetime date of the respirator (expiry date).
	Read the user's manual before using the respirator.
	Storage temperature range for the respirator.
	Maximum humidity for the storage of the respirator.

Table 4

EU DECLARATION OF CONFORMITY

Subjects of declaration - product identification: Respirators: Extol® Premium 8856714 (FFP1); Extol® Premium 8856715 (FFP1)+valve; Extol® Premium 8856716 (FFP1)+valve; Extol® Premium 8856723 (FFP2); Extol® Premium 8856724 (FFP2)+valve; Extol® Premium 8856727 (FFP2); Extol® Premium 8856728 (FFP2)+carbon+valve; Extol® Premium 8856734 (FFP3)+valve; Extol® Premium 8856738 (FFP3)+carbon+valve

Manufacturer Madal Bal a.s. - Bartošova 40/3, CZ-760 01 Zlín - Company ID No.: 49433717 hereby declares, that the described products listed above are in conformity with the harmonisation legal regulation of the European Union: (EU) 2016/425. This declaration is issued under the exclusive responsibility of the manufacturer.

The harmonisation norm (including its amendments, if any exist), which was used in the assessment of conformity and on the basis of which the Declaration of conformity is issued: EN 149:2001 + A1:2009

Notified Body No. 2797; BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, Holland, carried out an EU type-examination according to module B and issued certificate no.: 751390 dated 10.11.2021.

The aforementioned personal protective products (respirators) are subject to the procedure for the assessment of conformity with the type based on ensuring the quality of the production process according to module D under the supervision of the aforementioned notified body. Continuously updated statement of conformity in manual, see the website www.extol.eu.

Place and date of issue of EU Declaration of Conformity: Zlín 10.11.2021

On behalf of Madal Bal, a.s.
Martin Šenkýř, Member of the Company's Board of Directors

Explanations for table 2

ATTENTION

- Layer of active carbon in the respirator (if included): Captures unpleasant non-toxic odours and gases.
- The total penetration through the respirator includes penetration along the contact line of the respirator with the face, penetration through the material of the filter and penetration through the exhalation valve, if the respirator is equipped with one.

¹⁾ Norm EN 529:2005 for recommendations regarding the selection of protective equipment for respiratory organs with effective protection according to class FFP1, FFP2 and FFP3 are based on a so-called nominal protection factor NPF, which is for class FFP1: 4, for class FFP2: 12 and for class FFP3: 50 and which is specified by many different respirator brands, however this factor NPF is specified only from the max. permitted penetration through the respirator given by norm EN 149+A1, according to the formula: 100/X% (total penetration in percent), which, however, does not take into consideration the toxicity of the substance and its permitted exposure limit according to national legislation (in the Czech Rep. according to NV 361-2007 Coll as amended) and which, therefore, in many countries differs specifically due to national legislation requirements, which are not harmonised. Table 3 specifies the mentioned (national) assigned protection factors (APF) for the individual respirator classes specified in the mentioned countries. For the assessment of the minimum level of required protection, it is necessary to calculate the minimum required protection factor as a ratio: of the concentration of the specific harmful substance outside the contact part / permitted concentration of harmful substances inside the contact part (permitted exposure limit) and to compare this with the national assigned protection factor APF in the given country, in which the respirator is used, and based on this, select the respirator class FFP1, FFP2 or FFP3 (see EN 529).

Filter class	Assigned protection factor APF used in the listed countries					
	EN 149	FIN	D	I	S	UK
FFP1	4	4	4	4	4	4
FFP2	10	10	10	10	10	10
FFP3	20	30	30	30	20	20

Table 3²⁾ At higher concentration of substance, select FFP2

ATTENTION

- A respirator with a filter class of FFP3 can be used as a very effective tool for reducing the risk of infection by viral particulates, however, it is necessary to keep in mind that the filtration efficiency of the respirator material is not 100% ("only" 99%) and that the total penetration through the respirator is not zero, but may be up to 2 % (according to norm EN 149+A1 the declared values of filtration efficiency and total penetration through the filtration half face mask must be met by at least 8 out of 10 tested samples, i.e. not all 10). Furthermore, it is necessary to stress that the filtration efficiency of the material is tested using a test aerosol with a flow rate of 95 l/min through the respirator with an aerosol particulate diameter in the range from 20 nm to 2000 nm, whilst the mean size of the aerosol particulates is 600 nm and the diameter of viral particulates, depending on the type of virus, is in the range from 23 nm (rhinovirus cold virus) - 63 nm (rubella/German measles togavirus) - 100 nm (flu virus 1 - orthomyxovirus) - 112 nm (coronavirus (SARS2)), however the flow rate of the test aerosol through the respirator is so great that statistically it covers even the smallest viral particulates, not however completely, and it thus follows that the respirator with class FFP3 cannot provide absolute protection against viruses, nevertheless can significantly reduce the risk of infection. To reduce the risk of infection it is no less important to correctly fit the respirator on the face and to wear gas-tight glasses to limit the penetration of harmful biological agents via the eyes.
- Note: the size of bacteria is significantly larger and is in the range from approx. 1000 nm length x approx 600 nm - 1500 nm width for rod-shaped bacteria.

ATTENTION

- The here provided examples of harmful substances in table 2 are general recommendations and for the protection of the user it is necessary to know the exact concentration of all harmful substance in the air and the permitted exposure limits for the specific harmful substance according to the legislation of the country in which the respirator is used. Assessment of the minimum required level of protection must relate to both the concentration of harmful substances with the highest toxicity as well as the concentrations of other harmful substance in the environment with lower toxicity.
- PEL: The permitted exposure limit to a chemical substance, dust, aerosol in the air, to which an employee may be exposed during an eight-hour or shorter weekly work shift, see. NV. 361/2007 Coll. as subsequently amended.
- The requirement for the minimum filtration efficiency of the respirator material and the total penetration through the respirator for the given class FFP1; FFP2 and FFP3 is specified by harmonisation norm EN 149+A1.
 - Total penetration includes parts: penetration through the sealing line part of the half face mask, penetration through the material of the filter and penetration through the exhalation valve (if part of the respirator).

SAFETY WARNINGS FOR THE USE OF RESPIRATORS

- The respirator does not protect against gases and lower oxygen content in air.
- The respirator must not be used for protection in an environment where the composition and concentration of all harmful substances in the air are unknown.
- The respirator must not be used for longer than the duration of one work shift, thereafter it must be disposed of. According to EN 149+A1 a respirator used for a duration of no more than a single work shift is considered to be disposable. Its lifetime is, however, dependent on the concentration of particulates in the workplace and the activity of the user, i.e. at a higher particulate concentration and higher breathing frequency of the user it must be replaced with a new one sooner than the duration of a single work shift.