

PRODUCT TECHNICAL DESCRIPTION

Nano respirator SPURTEX® V100 FFP2 NR made from nanostructured filtration material SPURTEX® PP – product for protection of human respiratory system against solid particles, bacteria, and viruses.

PRODUCT DESCRIPTION

Single-use respirator classified as FFP2 NR (according to EN 149:2001+A1:2009) made of unique nanostructured filtration material SPURTEX® PP L2 V3 provides effective and active protection of human respiratory system especially in the capture of ultrafine particles in size from 20 to 400 nm, i.e. including viruses with size from 30 to 150 nm. Based on a test report from Nelson Labs (USA): SPURTEX® nano respirators filter 99.9 % of bacteria (BFE), viruses (VFE) and solid particles (PFE) with the size of 0.3 µm.

CONSTRUCTION AND USED MATERIALS

Nano respirator SPURTEX® V100 FFP2 NR is produced by ultrasonic welding technology. The pair of elastic loops and a thin nose metal clip ensure that the respirator is fixed on face perfectly and comfortably fits on the nose.

Construction is convex type without exhalation valve.

Standard colour version is both-sides white.



Maximum dimensions in packed state (mm)	Thickness (mm)	Weight (g)
115 x 165	2–4	5,8-6,8

Nano respirator SPURTEX® V100 FFP2 NR is made of special 7-ply SPURTEX® PP filtration material of which outer layers are based on polypropylene and polyester non-woven textiles and inner active nanofiber filtration membrane made from PVDF (polyvinylidene fluoride) polymer by special state-of-art technology based on electrospinning of conductive polymer solution. Respirator SPURTEX® V100 FFP2 NR is free of highly brittle borosilicate glass microfibres sometimes used in standard respiratory protective equipment which have negative ecological and especially health impacts (small sharp needle-shaped particles possibly split off during their usage have potentially carcinogenic effect).



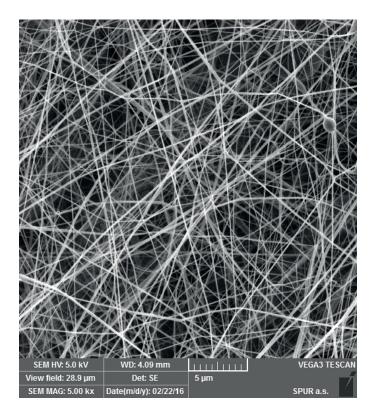


Nanofiber filtration polymer layer is tightly fixed between outer layers which guarantees reasonable mechanical properties of the final product and eliminates damage of ultrafine polymeric nanofibers during manipulation and using.

Based on expert opinions, outer layers which are in contact with skin (PP non-woven textiles) are free of any significant skin irritants.

MATERIAL SPECIFICATION

Material SPURTEX® PP L2 V3 from which the Nano respirator SPURTEX® V100 FFP2 NR is produced fully meets EN149:2001+A1:2009 requirements for filtration half-masks against particles and is categorized as FFP2 NR protection class. However, unique nanofiber filtration layer of material SPURTEX® PP L2 V3 has outstanding filtration efficiency in the ultrafine particles area (20–400 nm) and thus, it is ideal for capturing of all sorts of bacteria or viruses (SARS-CoV-2 virus has real size between 80 and 150 nm). Moreover, these filtration properties are reached at ultralow pressure drops which significantly increases respirator breathing comfort and simultaneously decreases leakage between the respirator edge and face which further eliminates possible risk of unwanted particles or microorganism's penetration through this area.



Typical nanostructure of SPURTEX® PP L2 V3 filtration material (SEM microscope, magnitude 5000x).





TECHNICAL PARAMETERS

Use	single-use (NR)
Ergonomic shape	yes
Fixation	two elastic loops on sides for fixation around ears
Exhalation valve	without
Protection class	FFP2
Filtration efficiency/capture	capture aerosols, dust, smog, or pollen particles, effectively blocks particles with size of 80–150 nm (viruses)
Meets standard EN 149:2001+A1:2009	yes
Medical harmless	yes (based on expert opinions for all components)

Classification of respirator SPURTEX® V100 FFP2 NR according to EN 149:2001+A1:2009

Description	aerosol	Initial NaCl	Concetration of CO ₂ in exhalation air (vol. %)	Respiratory resistances						
		aerosol penetration		Inhalation resistance Exhal		Exhalatio	ation resistance at 160 Lmin ⁻¹ at head position			
		at 95 l. min ⁻¹ (%)		at 30 l.min ⁻¹ (Pa)	at 95 l.min ⁻¹ (Pa)	ahead (Pa)	down (Pa)	up (Pa)	left (Pa)	right (Pa)
Norm EN 149	FFP2	Max. 6 %	Max. 1 %	70	240	300	300	300	300	300
SPURTEX® V100 FFP2 NR1	FFP2	0,89	0,43	55	188	289	286	287	287	287

^{&#}x27;Measured at the Research Institute of Occupational Safety (RIOS) testing laboratory accredited by Czech Accreditation Institute according to EN ISO/IEC 17025:2018 (testing protocol No. 1024/ZZ-063/2020 which was used for certification protocol No. 1024/E-071/2020).

RISK ANALYSIS

Nano respirator SPURTEX® V100 FFP2 NR protects user against solid (dust, smoke) as well as liquid (droplets including bacteria and/or viruses) aerosols.

Usage		Important information	
Cutting, drilling, painting	Cement Wood Steel	In the case of silicone dioxide particles, respirator FFP3 must be used	
	Coating Varnishing Anti-corrosion coating	Respirator for special purpose may be required	
Sprayed oil at low temp	eratures		
Soldering		In some countries FFP3 class may be required – see national rules	
Work with glass and mi	neral fibers		
Waste sorting		Respirator for special purpose may be prioritized Mask with filters against gases or vapours may be required	
Spraying Paint spraying Pesticides (water diluted)		Mask with filters against gases or vapours may be required	
Allergy Grain dust Pollen			
Contact with:	Moulds/fungi Exhaust gases/smoke Smog		
	Bacteria/viruses	FFP3 class is normally required. However, unique SPURTEX® PP nanofiber membrane of respirator SPURTEX® V100 FFP2 NR effectively captures particles of 30–150 nm in size (viruses)	

Note: This table provides basic information only. It should not be used as the sole source for respirator choose. Details on functional properties and limitations are given on the respirator package and in the user manual. Before using the respirator, the user must read and understand the instructions for use of the product. Local regulations must be complied. Please note that these uses indicate some of the risks that may be considered. The selection of the most appropriate respiratory protective equipment (ROP) depends on the specific situation and is always carried out exclusively by a qualified worker familiar with the actual working conditions and limitations of respiratory protective equipment.





RISK ASSESSMENT

Nano respirator SPURTEX® V100 FFP2 NR made of SPURTEX® PP filtration membrane is classified as single-use product. The recommended usage is for medium levels of fine dust particles and water-or oil-based aerosols which usually occur at work with plasterboard, cement, at grinding, and work with wood sawdust. However, due to its unique filtration properties of ultrafine particles (20–400 nm), it is possible to use it also in microbiologically contaminated environment (bacteria/viruses). Nevertheless, in this case, its filtration properties are kept up for very limited time only, based on the contamination level. In such environment, significant number of dangerous microorganisms can be concentrated on the nanofiber filter and thus, it is necessary to change it frequently. Nanofiber filtration structure has no antibacterial or antivirus treatment.

LIST OF THE ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

The assessment of conformity with the essential health and safety requirements according to Annex II to Regulation (EU) 2016/425 of the European Parliament and of the Council was performed by Notified Body No. 1024 according to the following list.

1.	General requirements applicable to all PPE
1.1	Design principles
1.1.1.	Ergonomics
1.1.2.	Levels and classes of protection
1.1.2.1.	Optimum level of protection
1.1.2.2	Classes of protection appropriate to different levels of risk
1.2	Innocuousness of PPE
1.2.1	Absence of inherent risks and other nuisance factors
1.2.1.1	Suitable constituent materials
1.2.1.2	Satisfactory surface condition of all PPE parts in contact with the user
1.2.1.3	Maximum permissible user impediment
1.3	Comfort and effectiveness
1.3.1	Adaptation of PPE to user morphology
1.3.2	Lightness and strength
1.4	Manufacturer's instructions and information
	In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:
	a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;
	b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;
	d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;
	e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;
	f) where applicable, the type of packaging suitable for transport;
	h) the risk against which the PPE is designed to protect;
	i) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;
	j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;
	k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;
	l) the internet address where the EU declaration of conformity can be accessed.
3.	Additional requirements to particular risks
3.10	Protection against substances and mixtures which are hazardous to health and against harmful biological agents
3.10.1	Respiratory protection





INSTRUCTION FOR USE

Respirator as well as its package must be visually checked before use. In case of any damage, do not use.

Nano respirator SPURTEX® V100 FFP2 NR must cover nose and mouth. Its fixation is ensured by two elastic ear loops and thin metal clip on the top of the mask which must be shaped by fingers around nose ridge.

Nano respirator SPURTEX® V100 FFP2 NR provides no protection against gases. Oxygen amount in the environment where respirator is used must be at least 17%.

Standard use of respirator is limited on one shift (8 hours) only. However, in case of use in strongly microbiologically active environment (bacteria/viruses), based on the contamination level, this time can be significantly shorted due to significant concentration of bacteria/viruses on the special nanofiber filter.









Washing or ironing the Nano respirator SPURTEX® V100 FFP2 NR is not recommended.

Product is declared as single-use however, in necessary cases (e.g. lack of respiratory protective equipment at epidemic or pandemic situations) during work in strong microbiologically active environment (bacteria/viruses) it is possible to sterilize it by germicidal (UV-C) lamps and use it repeatedly (3–5 times) when emergency. Other methods of sterilization at time of emergency are necessary to be discussed with the producer. Sterilization by hot steam is not recommended.

It is necessary to wear the Nano respirator SPURTEX® V100 FFP2 NR on smooth (i.e. shaven) face only. Beards prevent from flawless fixation on face and thus significantly decrease filtration efficiency.

Producer does not guarantee listed filtration properties of the Nano respirator SPURTEX® V100 FFP2 NR which is mechanically damaged (e.g. during transport or manipulation).

Nano respirator SPURTEX® V100 FFP2 NR cannot be used in explosive environment.

Detailed instructions for use in language of the country where the respirator is placed on the market are attached to every single package.

PACKAGING

1, 5 and 50 pcs in polyethylene bag (individual packaging), 600, 540 or 800 pieces in original paper box (bulk package suitable for transport). Paper boxes can be stored on the palettes. Packaging can be modified according to individual agreement with customer.

Marking of the product:

Nano respirator SpurTex® V100 FFP2 NR, producer: SPUR a.s. Convex type without exhalation valve in FFP2 NR class (single use).

Categorized according to standard EN 149:2001+A1:2009. Lifetime 5 years (individual and bulk packaging) while stored at temperatures of 10–30°C and humidity of max. 50%. Expiration date is declared on each package. Do not store on sunlight.







Even

10-30 °C

max. 50 %

Expiration date must be checked before use.

For proper use please read instructions for use attached to each package.





STORAGE

Nano respirator SPURTEX® V100 FFP2 NR can be stored in the original individual package for 5 years, in special bulk package even for 10 years at temperatures of 10–30°C and humidity of maximum 50%. This is allowed due to special innovative solution based on primarily mechanical not electrostatic capturing of solid particles/microorganisms by nanofiber filtration membrane SPURTEX®. Filtration efficiency of filtration materials based on electrostatic capturing (typically melt blown non-woven textiles) can significantly decrease in time.

Polymer materials of which the nano respirators SPURTEX® V100 FFP2 NR are produced (i.e. polyester – PES, polypropylene – PP, polyvinylidene fluoride – PVDF), are generally very stable to degradation (deterioration of functional properties) caused by ambient gases (especially oxygen and ozone) and by humidity and thermal stress within the common laboratory temperatures. These materials are less resistant when exposed to UV light for a long time.

Storage areas must be without direct sunlight and other sources of UV light. It is also necessary to secure the storage area from insect and other animals. Packed respirators cannot be stored together with chemicals, sprays, fertilizers, contaminated materials, or other biologically dangerous materials which can express even minimal level of risk of contamination.

For a short-term storage of individually packed respirators for a period of 5 years the defined stable conditions without presence of direct sunlight must be kept.

During a long-term storage of bulk packages of respirators, the packages must be stored on certified wooden EU pallets. The packaging must be properly secured by binding tapes to avoid a fall of boxes during manipulation. The respirators cannot be repacked or store individually without outer paper boxes. This could significantly shorten the lifetime of the respirators.

According to customer requirements special packaging can be made which can ensure 10 years product lifetime. The material stability is guaranteed for this period if defined storage conditions are kept and special bulk package is not mechanically broken. Special bulk packaging contains vacuum barrier foil based on ethylene vinyl alcohol (EVOH) or special aluminium layer which can together with directed crystallinity and polymer chains orientation decrease diffusion coefficient. This packaging of respirators must also contain a pack with silica gel for damp absorption.

Persons who manipulate with packed Nano respirators SPURTEX® V100 FFP2 NR must be properly trained and all transport conditions mentioned in the section "Storage" must be ensured and guaranteed during transport and manipulation (i.e. during whole logistic process).

LEGISLATION

Nano respirator SPURTEX® V100 FFP2 NR is in conformity with the regulation (EU) 2016/425 of the European Parliament and the Council on personal protective equipment. EU-type examination was performed by notified body No. 1024 (Research Institute of Occupational Safety, p.r.b.) according to standard EN 149:2001+A1:2009.

Technical Data Sheet, Instruction for Use and valid EU Declaration of Conformity are available online at producer's website (www.spur.cz)

DISPOSAL

Contaminated respirators SPURTEX® V100 FFP2 NR must be disposed as dangerous waste in accordance with local regulations.

NOTICE

Producer has no liability (responsibility), either directly or indirectly, for any damages caused by incorrect application or use of respirator SPURTEX® V100 FFP2 NR.

Issue date: November 24, 2020

