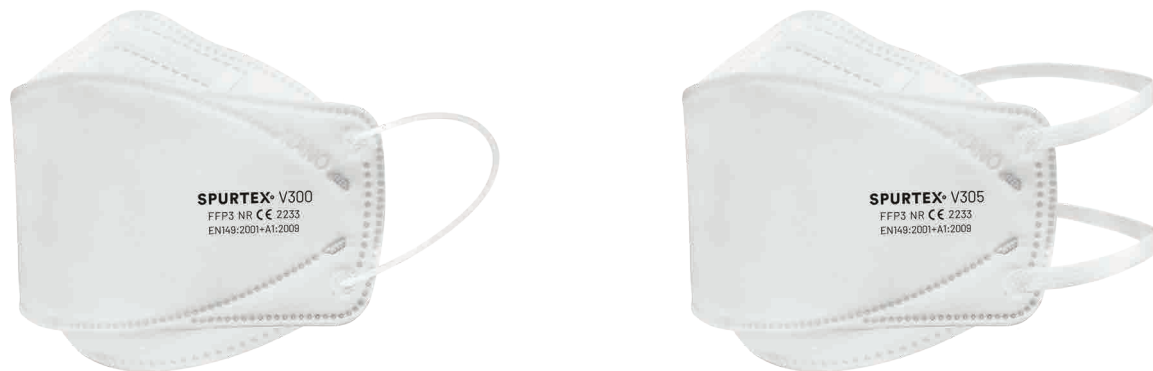


PRODUCT TECHNICAL DESCRIPTION

Nano respirator SPURTEX® FFP3 NR V300L, V300M, V305L, V305M made from nanostructured filtration material SPURTEX® PP – product for active protection of human respiratory system against solid and liquid aerosols as well as bacteria and viruses

PRODUCT DESCRIPTION

Single-use respirator classified as FFP3 NR (according to EN 149:2001+A1:2009) made of unique nanostructured filtration material SPURTEX® PP 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 typical 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.



USED MATERIALS

Nano respirators SPURTEX® FFP3 NR V300L, V300M, V305L, V305M are made of special SPURTEX® PP L3 V1 filtration materials respectively of which outer layers are based on polyester and polypropylene non-woven textiles and inner active polymer nanofiber filtration membrane produced by special state-of-art technology – electrospinning of conductive polymer solution. Nano respirators SPURTEX® FFP3 NR V300L, V300M, V305L, V305M are free of highly brittle borosilicate glass microfibrils 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).

Polymer nanofiber filtration 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 (PP non-woven textiles), elastic yarns and foamed nose sealing which are in contact with skin are free of any significant skin irritants.

MATERIAL SPECIFICATION

Material SPURTEX® PP L3 V1 from which the Nano respirators SPURTEX® FFP3 NR V300L, V300M, V305L, V305M are produced respectively, fully meets EN 149:2001+A1:2009 requirements for filtration halfmasks against particles and are categorized as FFP3 protection class. However, unique nanofiber filtration layer of material SPURTEX® PP L3 V1 has outstanding filtration efficiency in the area of ultrafine particles (20–400 nm) and thus, it is ideal for capturing of all sorts of viruses (SARS-CoV-2 virus has real size between 80 and 150 nm). Unique filtration properties have also been proved by special testing in Nelson Labs (USA) – details see in Table below. Moreover, these filtration properties are reached at low pressure drops which significantly increases respirator breathing comfort and simultaneously decreases possible leakage between the respirator edge and face which further eliminates possible risk of unwanted particles or microorganisms penetration through this region. Moreover, both filtration materials can be produced with antimicrobial protection which effectively deactivates bacteria and viruses. Production of the material SPURTEX® PP L3 V1 fully meets ISO 9001 and ISO 28000 standards.

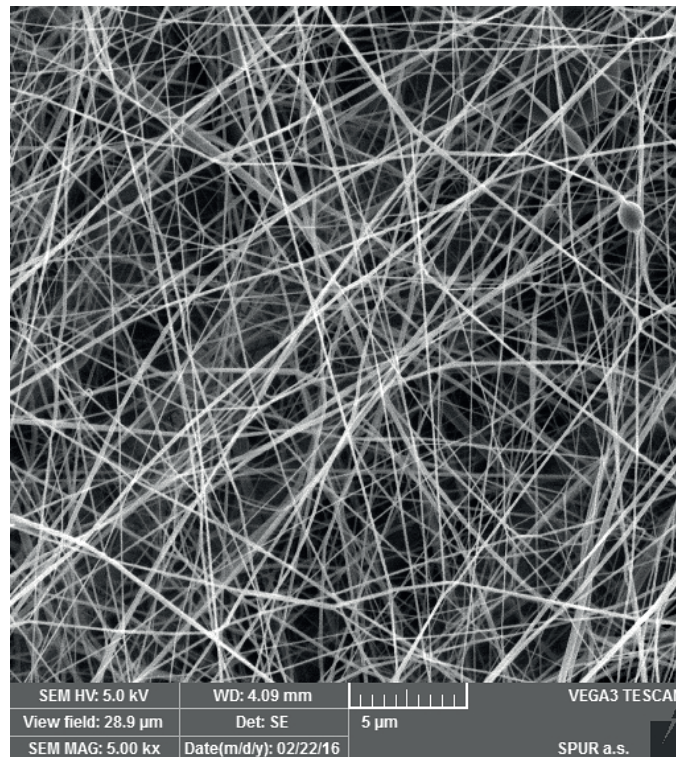
Parameter	Standard	Particle challenge type	Head velocity (cm.s ⁻¹) ¹	Value (%)
Bacterial filtration efficiency (BFE)	ASTM F2101-19, EN 14683	Staphylococcus aureus	11,8	>99,9 ²
Viral filtration efficiency (VFE)	adapted from ASTM F2101	bacteriophage ΦX174	11,8	>99,9 ²
Particle filtration efficiency (PFE)	ASTM F2299	0.3 μm latex polystyrene spheres	5,2	99,9916 ⁴

¹To compare: head velocity according to EN 143 and EN 149 is 5,7 cm.s⁻¹ (air flow 30 L.min⁻¹) and 18 cm.s⁻¹ (air flow 95 L.min⁻¹)

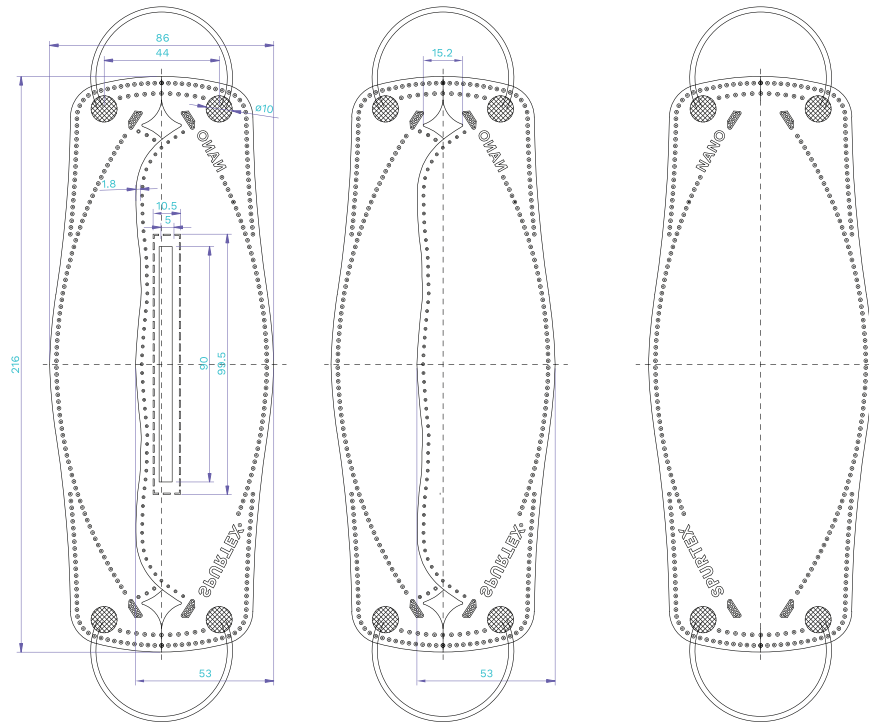
²based on test report from Nelson Labs (USA) No. 1350072-S01

³based on test report from Nelson Labs (USA) No. 1350073-S01

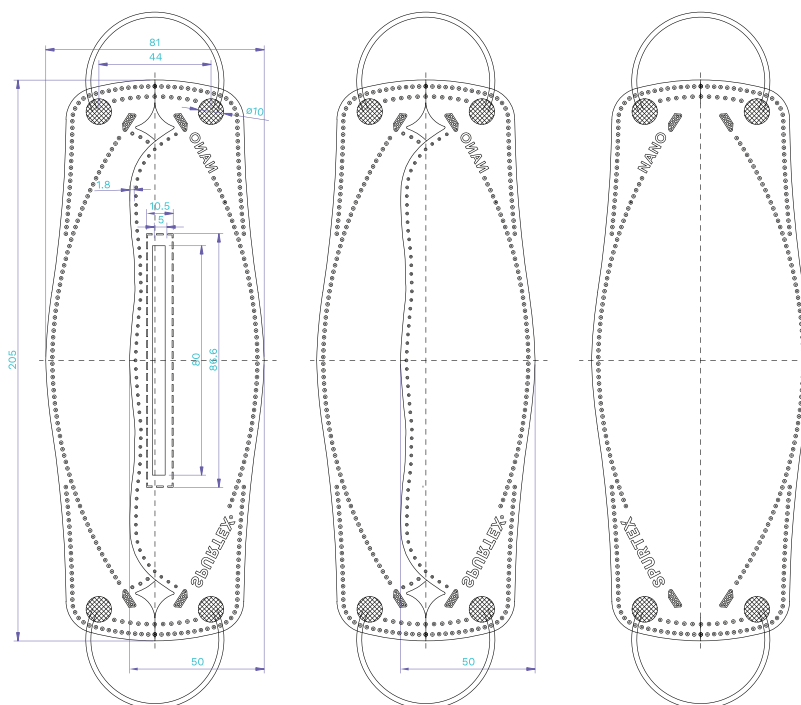
⁴based on test report from Nelson Labs (USA) No. 1350074-S01



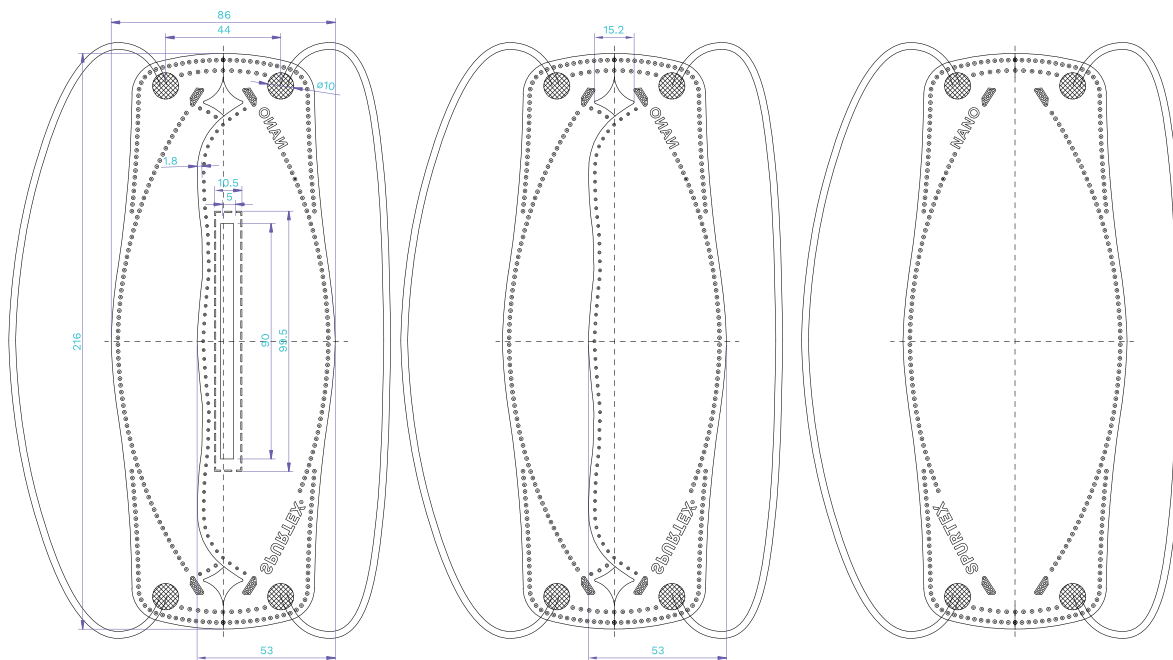
Typical nanostructure of SPURTEX® PP L3 V1 filtration material (SEM microscope, magnitude 5000x).



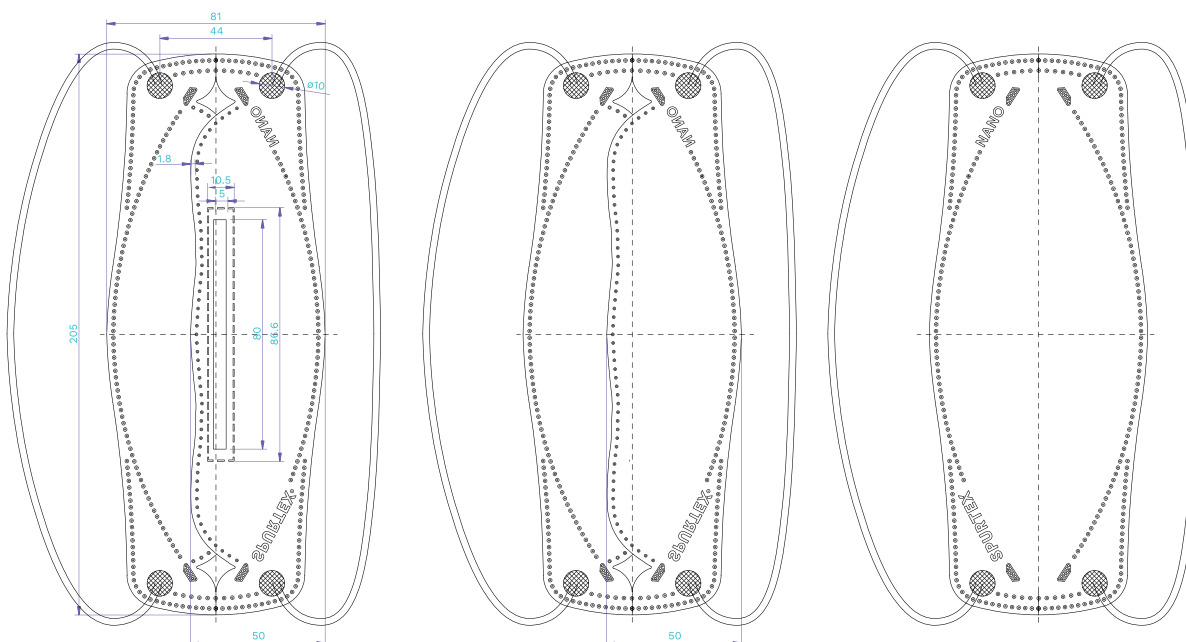
Technical drawing of valveless respirator V300L.



Technical drawing of valveless respirator V300M.



Technical drawing of valveless respirator V305L.



Technical drawing of valveless respirator V305M.

DESIGN

Nano respirators SPURTEX[®] FFP3 NR V300L, V300M, V305L, V305M are produced from material SPURTEX[®] PP L3 V1 respectively by ultrasonic welding technology. Design contains three connected parts which can after unfold easily fit each individual head morphology and ensure necessary comfort during wearing and using. Shape is designed as convex “fish type”) – see Table below.

Version	Size	Particle challenge type	Exhalation valve	Colour
V300L	standard	on head with plastic extender	no	white
V300M	small	on head with plastic extender	no	white
V305L	standard	on head	no	white
V305M	small	on head	no	white

Sizes of individual versions with production tolerances are summarized in Table below.

Version	Size	Particle challenge type
V300L	standard	215±5 x 87±5
V305L		
V300M	small	204±5 x 83±5
V305M		

TECHNICAL PARAMETERS

Use	single-use (NR)	
Ergonomic shape	yes	
Fixation	V300L, V300M	fixation on ears + plastic extender
	V305L, V305M	fixation on head
Exhalation valve	no	
Protection class	FFP3	
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 in contact with skin)	

Classification according to EN 149:2001+A1:2009

Standard/ respirator version	Protection Class	Initial NaCl aerosol penetration at 95 L.min ⁻¹ (%)	Initial paraffin oil aerosol penetration at 95 L.min ⁻¹ (%)	Maximal concentration of CO ₂ in exhalation air (vol. %)	Breathing resistances						
					Inhalation resistance		Exhalation resistance at 160 L.min ⁻¹ at head position				
					at 30 L.min ⁻¹ (Pa)	at 95 L.min ⁻¹ (Pa)	forward (Pa)	down (Pa)	up (Pa)	on the left (Pa)	on the right (Pa)
Norm EN 149	FFP3	Max. 1	Max. 1	1	Max. 100	Max. 300	Max. 300	Max. 300	Max. 300	Max. 300	Max. 300
V300L, V300M, V305L, V305M ¹	FFP3	0,48	0,32	0,44	51	158	277	278	277	277	277

¹Measured on samples of the respirator at the GÉPTESZT Termelőeszközök Felülvizsgáló és Karbantartó, testing laboratory accredited by HAC according to EN ISO/IEC 17025:2018 (Testing protocol no. VD-34-2021-227 which was used for certification protocol no.VD35/227/2104/E/2233)

RISK ANALYSIS

Nano respirators SPURTEX® FFP3 NR V300L, V300M, V305L, V305M protects user against solid as well as liquid aerosols including harmful biological agents (bacteria/viruses). Detailed risk analysis is provided in table below.

Usage	Important information
Cutting, drilling, painting Cement Wood Steel Coating Varnishing Anti-corrosion coating	Respirator for special purpose may be required
Reconstruction works Scratching, crushing plasters Terrestrial works Foam and insulation spraying	Demolition works are not included
Sprayed oil at low temperatures	
Soldering	
Work with glass and mineral 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 Bacteria/viruses	
Industrial applications Rubber and plastic processing Oil extraction and processing Pharmacy Processing of powder additives and chemicals	Mask with filters against gases or vapours may be required

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 respirators SPURTEX® FFP3 NR V300L, V300M, V305L, V305M made of SPURTEX® PP L3 V1 filtration membrane respectively are 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 their unique filtration properties of ultrafine particles (20–400 nm), it is possible to use them also in environment contaminated by harmful biological agents (bacteria/viruses). However, filtration properties are kept up for very limited time only, based on the contamination level.

LIST OF THE ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

Conformity assessment with basic requirements on health protection and safety according to Appendix II Regulation (EU) 2016/425 of the European Parliament and of the Council was performed by Notified body No. 2233 according to 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 it. Nano respirator SPURTEX® FFP3 NR V300L, V300M, V305L, V305M must completely cover nose and mouth.

Fixation of versions V300L and V300M is designed as pair of elastic yarns on head with plastic extender and thin metal clip with foamed sealing on the top of the mask which must be shaped by fingers around nose ridge (see following scheme on the left).

Fixation of versions V305L and V305M is designed as pair of elastic yarns on head and thin metal clip with foamed sealing on the top of the mask which must be shaped by fingers around nose ridge. Firstly, top elastic yarn is drag over the top of the head and bottom elastic yarn is drag over ears. Secondly, thin metal band on the top of respirator is shaped by fingers to copy nose region (see following scheme on the right).

Nano respirators SPURTEX® FFP3 NR V300L, V300M, V305L, V305M provide no protection against gases. Oxygen amount in the environment where these respirators are used must be at least 17%.

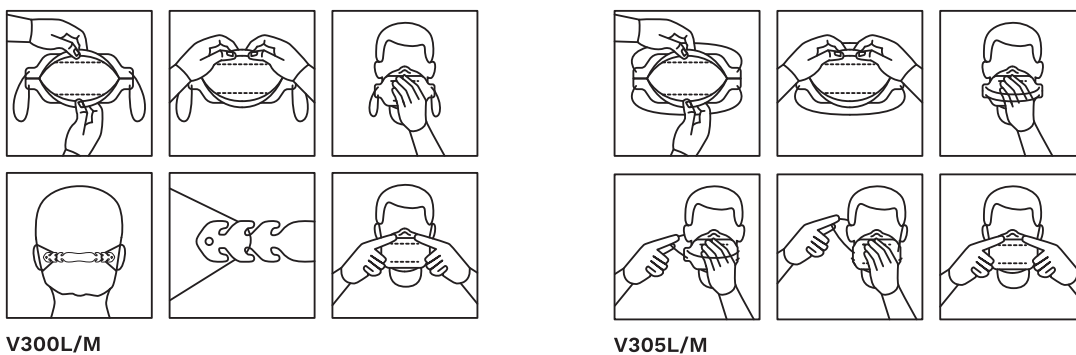
Standard use of respirator SPURTEX® FFP3 NR V300L, V300M, V305L, V305M is limited on one shift (8 hours) only. However, in the case of use in environment strongly contaminated by harmful biological agents (bacteria/viruses), this time can (based on the contamination level) be significantly shorted due to significant concentration of harmful biological agents on the special nanofiber filter.

Washing or ironing of nano respirators SPURTEX® FFP3 NR V300L, V300M, V305L, V305M 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 environment strongly contaminated by harmful biological agents (bacteria/viruses) it is possible to emergency sterilize it by special liquid SPURTEX® Unisanol (spray several times from both sides and then wait several minutes to evaporate the disinfection). Other methods for emergency sterilization (germicidal UV-C lamps, ozone, hot air etc.) must be discuss with manufacturer. Sterilization under hot steam is not recommended.

It is necessary to wear the Nano respirators SPURTEX® FFP3 NR V300L, V300M, V305L, V305M 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 respirators SPURTEX® FFP3 NR V300L, V300M, V305L, V305M which are mechanically damaged (e.g. during transport or manipulation).

Nano respirators SPURTEX® FFP3 NR V300L, V300M, V305L, V305M cannot be used in explosive environment.



PACKAGING

1, 3 and 10 pieces in polyethylene bag (individual package), bulk packages with amounts of respirators according to individual agreement with customer are realized in original paper boxes suitable for transport on palletes.

Marking of the product:

Nano respirator SPURTEX[®] FFP3 NR V300L, V300M, V305L or V305M producer: SPUR a.s.

Convex type with or without exhalation valve (based on version) in FFP3 NR protection class (single-use).

Categorized according to standard EN 149:2001+A1:2009.

Lifetime 5 years, store at temperatures of 10–30°C and humidity of max. 50%. Expiration date is declared on each individual package. Do not store on direct sunlight.



5 years



10–30 °C



max. 50 %

Expiration date must be checked before use.

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

STORAGE

Polymer materials of which the nano respirators SPURTEX[®] FFP3 NR V300L, V300M, V305L, V305M are produced (i.e. polyester – PES and polypropylene – PP) 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.

Persons who manipulate with packed Nano respirators SPURTEX[®] FFP3 NR V300L, V300M, V305L, V305M must be properly trained and during transport and manipulation (whole logistic process) must ensure and guarantee such transport conditions which are mentioned in the section “Storage”.

LEGISLATION

Based on Regulation (EU) 2016/425 of the European Parliament and the Council the Declaration of Conformity of Nano respirators SPURTEX[®] FFP2 NR V300L, V300M, V305L, V305M was according to the EN 149:2001+A1:2009 standard performed by notified body No. 2233 (GÉPTESZT Termelőeszközöket Felülvizsgáló és Karbantartó Kft., Jablonka u. 79, 1037 Budapest, Hungary).

Technical documentation, instruction for use and valid Declaration of Conformity are freely available online on producer website (www.spur.cz).

DISPOSAL

Contaminated Nano respirators SPURTEX[®] FFP3 NR V300L, V300M, V305L, V305M 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 Nano respirators SPURTEX[®] FFP3 NR V300L, V300M, V305L, V305M.



Protocol PN 260 006

Certificate no. VD35/227/2104/E/2233

Issue date: 1st June, 2021

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