PERISTEGRAF srl
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PERISTEGRAF FOLDABLE DISPOSAL RESPIRATORS

FFP2

TECHNICAL FILE

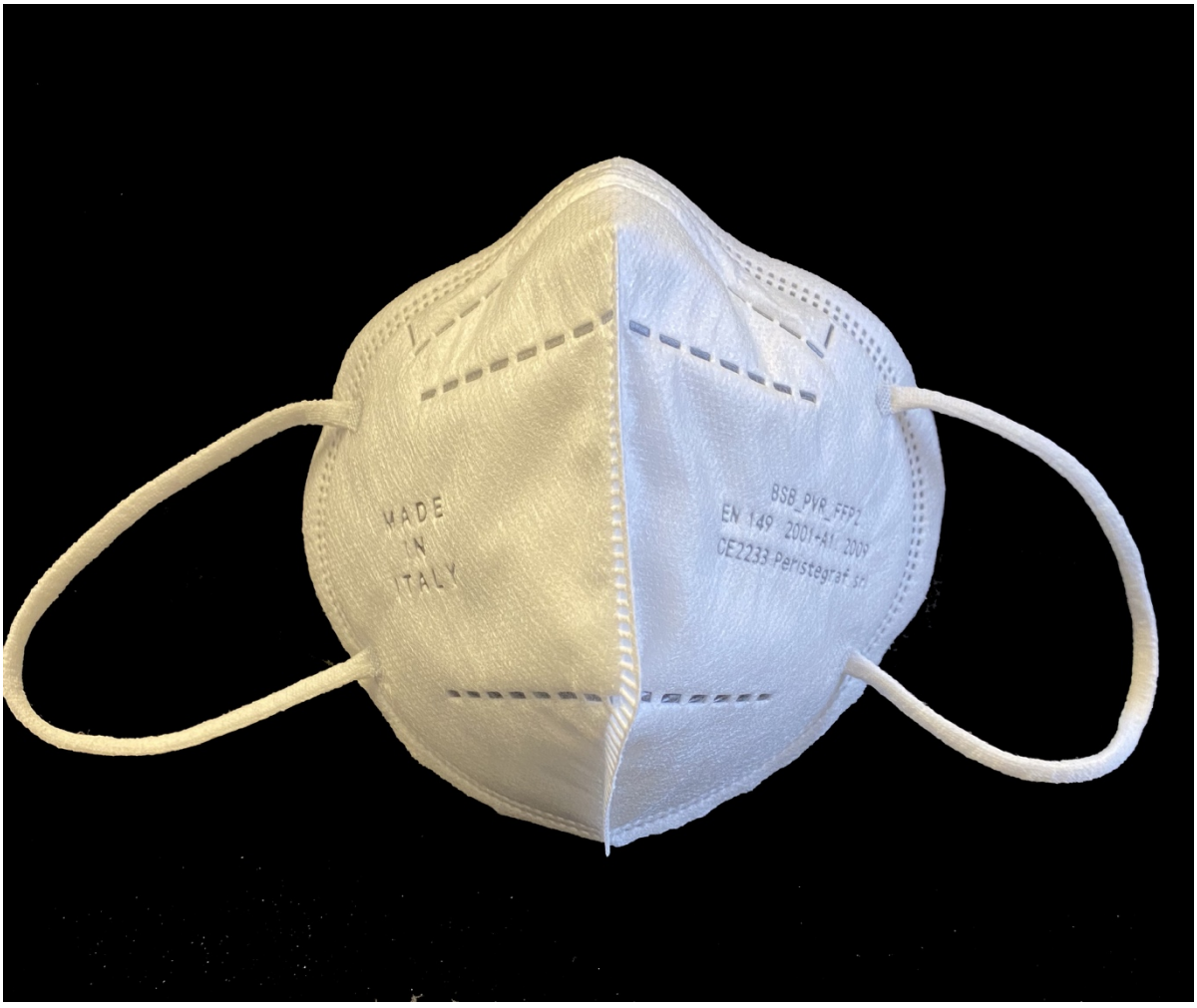
This Technical Documentation has been prepared according to the guidelines and contents of Annex III – Regulation (EU) 2016/425, with the aim of accompanying the certification by the appropriate Notified Body, following the compliance tests to EN 149:2001 - A1:2009.

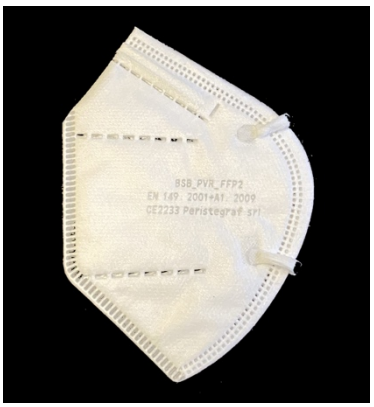
SUBMITTED BY NAME:	Antonio Boccia
SUBMITTED BY DATE:	22/10/2020
STATEMENT:	**The signature below is to confirm that the statements, information and declarations within this technical file are true and accurate.**
SIGNATURE:	Peristegraf srl Via Giacomo Peroni 130 - 00131 Roma Tel. 06 96035140 - Fax 06 96036338 P.iva 01768221002 - C.f. 07404600582

General Information

MANUFACTURER NAME:	PERISTEGRAF SRL
MANUFACTURER ADDRESS:	Via Giacomo Peroni, 150 – 00131 Roma (RM) (Italy)
	Operations: Via Giacomo Peroni, 150 – 00131 Roma (RM) (Italy)
PRODUCT TYPE:	Half-Face RESPIRATOR
APPLICABLE STANDARDS:	EN 149:2001+A1:2009
MODEL IDENTIFICATION:	BSB_PVR_FFP2 NR
PERFORMANCE CLASSIFICATION:	FFP2 NR
TECHNICAL FILE REFERENCE:	SS-TF001.01
DATE AND REVISION CONTROL:	Rev.01 08/10/2020

Product Images





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1. AUTHORISED REPRESENTATIVE	
Authorised representative appointed?	NO
Company Name:	
Full Postal Address:	
DECLARATION N/A	
NAME:	**DATE:**

2. INTENDED USE OF THE PPE

The Peristegraf respirator model BSB_PVR_FFP2 NR, is a facial half-mask; no-valve, for professional and working use for one shift (8hrs).
Classified as Personal Protective Equipment (PPE) category III, it is designed to protect the respiratory tract from contaminants and viruses.

3. TECHNICAL SPECIFICATION OR HARMONIZED STANDARDS

This section is split into two parts. (3.1) should be completed if a technical specification has been used, and (3.2) should be completed if harmonized standards have been used.

3.1 TECHNICAL SPECIFICATION

A technical specification is used typically where there is no appropriate harmonized standard, or there is a gap in harmonized standards requiring a technical specification to be produced. A technical specification can incorporate some clauses of harmonized standards. Where a technical specification has been used, please complete the below.

Technical specification used?	NO
Harmonized standard(s) clauses used?	NO
STANDARD NUMBER & DATE OF PUBLICATION	**CLAUSE NUMBERS USED**

3.2. HARMONIZED STANDARDS

Please list all of the harmonized standards applicable to the product to test conformity to the EHSRs and confirm if the standard has been used in full. If only some clauses of a standard have been applied, those clauses should be listed.

STANDARD & DATE	FULL OR PART USED	CLAUSE NUMBERS USED
EN 149:2001+A1:2009	Has been used in full? YES	Full test

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
1	**GENERAL REQUIREMENTS APPLICABLE TO ALL PPE**					
	PPE must provide adequate protection against the risks against which it is intended to protect.	YES	EN 149:2001+A1:2009			
1.1	**Design principles**					
1.1.1	***Ergonomics***					
	PPE must be designed and manufactured so that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest level possible.	YES	EN 149:2001+A1:2009 5 / 7.7 / 7.9			
1.1.2	***Levels and classes of protection***					
1.1.2.1	***Optimum level of protection***					
	The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or the normal performance of the activity.	YES	EN 149:2001+A1:2009 5 / 7.7 / 7.9 / 7.12			
1.1.2.2	***Classes of protection appropriate to different levels of risk***					
	Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.	YES	EN 149:2001+A1:2009 7.9			
1.2	**Innocuousness of PPE**					
1.2.1	***Absence of inherent risks and other nuisance factors***					
	PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.	YES	EN 149:2001+A1:2009 7.12 / 7.14 / 7.16			
1.2.1.1	***Suitable constituent materials***					
	The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.	YES	EN 149:2001+A1:2009 7.5 / 7.7 / 7.10 / 7.11			
1.2.1.2	***Satisfactory surface condition of all PPE parts in contact with the user***					

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		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.	YES	EN 149:2001+A1:2009 7.7 / 7.8			
1.2.1.3	***Maximum permissible user impediment***					
	Any impediment caused by PPE to the actions to be carried out, the postures to be adopted and sensory perceptions shall be minimised. Furthermore, use of the PPE must not engender actions which might endanger the user.	YES	EN 149:2001+A1:2009 7.7 / 7.14			
1.3	**Comfort and effectiveness**					
1.3.1	***Adaptation of PPE to user morphology***					
	PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.	YES	EN 149:2001+A1:2009 7.7			
1.3.2	***Lightness and strength***					
	PPE must be as light as possible without prejudicing its strength and effectiveness.	YES	EN 149:2001+A1:2009 7.4 / 7.5 / 7.7			
	PPE must satisfy the specific additional requirements in order to provide adequate protection against the risks for which it is intended and PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.	YES	EN 149:2001+A1:2009 7.4 / 7.5 / 7.7			
1.3.3	***Compatibility of different types of PPE intended for simultaneous use***					
	If the same manufacturer places on the market several PPE models of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.	NO				
1.3.4	***Protective clothing containing removable protectors***					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

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		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	Protective clothing containing removable protectors constitutes PPE and shall be assessed as a combination during conformity assessment procedures.	NO				
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:	YES	EN 149:2001+A1:2009 10	X		
	(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;	YES	EN 149:2001+A1:2009 10	X		
	(b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;	YES	EN 149:2001+A1:2009 10	X		
	(c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;	NO				
	(d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;	YES	EN 149:2001+A1:2009 10	X		
	(e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;	YES	EN 149:2001+A1:2009 10	X		
	(f) where applicable, the type of packaging suitable for transport;	YES		X		
	(g) the significance of any markings (see point 2.12);	YES	EN 149:2001+A1:2009 10	X		
	(h) the risk against which the PPE is designed to protect;	YES		X		
	(i) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;	YES		X		
	(j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;	YES	EN 149:2001+A1:2009 10	X		
	(k) references to the relevant harmonized standard(s) used, including the date of the standard(s), or references to the other technical specifications used;	YES			X	

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		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	(l) the internet address where the EU declaration of conformity can be accessed.	YES				
	The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.	YES				
2	**ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE**					
2.1	**PPE incorporating adjustment systems**					
	If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.	NO				
2.2	**PPE enclosing the parts of the body to be protected**					
	PPE must be designed and manufactured in a way that perspiration resulting from use is minimised. Otherwise it must be equipped with means of absorbing perspiration.	NO				
2.3	**PPE for the face, eyes and respiratory system**					
	Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.	YES	EN 149:2001+A1:2009 7.14	X		
	The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.	NO				
	If necessary, such PPE must be treated or provided with means to prevent misting-up.	NO				
	Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.	NO				
2.4	**PPE subject to ageing**					
	If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.	YES	EN 149:2001+A1:2009 9 / 10	X	X	

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		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, **his instructions** must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.	YES	EN 149:2001+A1:2009 9 / 10	X	X	
	Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be NBted or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.	NO				
2.5	**PPE which may be caught up during use**					
	Where the foreseeable conditions of use include, in particular, the risk of the PPE being caught up by a moving object thereby creating a danger for the user, the PPE must be designed and manufactured in such a way that a constituent part will break or tear, thereby eliminating the danger.	NO				
2.6	**PPE for use in potentially explosive atmospheres**					
	PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.	NO				
2.7	**PPE intended for rapid intervention or to be put on or removed rapidly**					
	Those types of PPE must be designed and manufactured in such a way as to minimise the time required for putting on and removing the equipment.	NO				
	Where PPE comprises fixing systems enabling the PPE to be maintained in the correct position on the user or removed, it must be possible to operate such systems quickly and easily.	NO				
2.8	**PPE for intervention in very dangerous situations**					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

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Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.	YES	EN149:2001 10	X		
	The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.	YES	EN149:2001 10	X		
	Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.	NO				
2.9	**PPE incorporating components which can be adjusted or removed by the user**					
	Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.	NO				
2.10	**PPE for connection to complementary equipment external to the PPE**					
	Where PPE incorporates a connexion system permitting its connection to other complementary equipment, the means of attachment must be designed and manufactured in such a way as to enable it to be mounted only on appropriate equipment.	NO				
2.11	**PPE incorporating a fluid circulation system**					
	Where PPE incorporates a fluid circulation system, the latter must be chosen or designed and placed in such a way as to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of the actions, postures or movements of the user under the foreseeable conditions of use.	NO				
2.12	**PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety**					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

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Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or indicators must, if possible, take the form of harmonized pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market.	YES	EN149:2001 9		X	
	Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.	NO				
2.13	**PPE capable of signalling the users presence visually**					
	PPE intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.	NO				
2.14	**Multi-risk PPE**					
	PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured in such a way as to satisfy, in particular, the essential health and safety requirements specific to each of those risks.	NO				
3	**ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS**					
3.1	**Protection against mechanical impact**					
3.1.1	***Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle***					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

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Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	PPE intended to protect against this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the means of shock-absorption would preclude effective use of the PPE for the foreseeable period of wear.	NO				
3.1.2	***Falls***					
3.1.2.1	***Prevention of falls due to slipping***					
	The outsoles of protective footwear intended to prevent slipping must be designed and manufactured or equipped with additional means so as to ensure adequate grip, having regard to the nature or state of the surface.	NO				
3.1.2.2	***Prevention of falls from a height***					
	PPE intended to prevent falls from a height or their effects must incorporate a body harness and a connexion system which can be connected to a reliable external anchorage point. It must be designed and manufactured so that, under the foreseeable conditions of use, the vertical drop of the user is minimised to prevent collision with obstacles while the braking force does not attain the threshold value at which physical injury or the opening or breakage of any PPE component which might cause the user to fall can be expected to occur.	NO				
	Such PPE must also ensure that, after braking, the user is maintained in a correct position in which he may await help if necessary.	NO				
	The manufacturer's instructions must specify, in particular, all relevant information relating to:	NO				
	(a) the characteristics required for the reliable external anchorage point and the necessary minimum clearance below the user;	NO				
	(b) the proper way of putting on the body harness and of attaching the connexion system to the reliable external anchorage point.	NO				
3.1.3	***Mechanical vibration***					

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		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.	NO				
3.2	**Protection against static compression of a part of the body**					
	PPE designed to protect a part of the body against static compressive stress must be sufficiently capable of attenuating its effects so as to prevent serious injury or chronic complaints.	NO				
3.3	**Protection against mechanical injuries**					
	PPE constituent materials and other components designed to protect all or a part of the body against superficial injuries, such as abrasion, perforation, cuts or bites, must be chosen or designed and incorporated so as to ensure that those types of PPE provide sufficient resistance to abrasion, perforation and gashing (see also point 3.1) under the foreseeable conditions of use.	NO				
3.4	**Protection in liquids**					
3.4.1	***Prevention of drowning***					
	PPE designed to prevent drowning must be capable of returning to the surface as quickly as possible, without danger to health, a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping the user afloat in a position which permits breathing while awaiting help.	NO				
	PPE may be wholly or partially inherently buoyant or may be inflated by gas which can be manually or automatically released, or inflated orally.	NO				
	Under the foreseeable conditions of use:	NO				
	(a) PPE must, without prejudice to its satisfactory operation, be capable of withstanding the effects of impact with the liquid medium and the environmental factors inherent in that medium;	NO				
	(b) inflatable PPE must be capable of inflating rapidly and fully.	NO				
	Where particular foreseeable conditions of use so require, certain types of PPE must also satisfy one or more of the following additional requirements:	NO				

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		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	(a) they must have all the inflation devices referred to in the second subparagraph, and/or a light or sound-signalling device;	NO				
	(b) they must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium;	NO				
	(c) they must be suitable for prolonged use throughout the period of activity exposing the user, possibly dressed, to the risk of falling into the liquid medium or requiring the user's immersion in it.	NO				
3.4.2	***Buoyancy aids***					
	Clothing intended to ensure an effective degree of buoyancy, depending on its foreseeable use, shall be safe when worn and afford positive support in the liquid medium. In foreseeable conditions of use, this PPE must not restrict the user's freedom of movement but must enable the user, in particular, to swim or take action to escape from danger or to rescue other persons.	NO				
3.5	**Protection against the harmful effects of noise**					
	PPE intended to prevent the harmful effects of noise must be capable of attenuating the latter so that the exposure of the user does not exceed the limit values laid down by Directive 2003/10/EC of the European Parliament and of the Council (1).	NO				
	Each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE. Should that not be possible, the labelling must be fixed to the packaging.	NO				
3.6	**Protection against heat and/or fire**					
	PPE designed to protect all or a part of the body against the effects of heat and/or fire must possess thermal insulation capacity and mechanical strength appropriate to the foreseeable conditions of use.	NO				
3.6.1	***PPE constituent materials and other components***					

	Constituent materials and other components intended for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be sufficiently incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use.	NO				

		YES /NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	Where the external surface of those materials and components must be reflective, the reflective power must be appropriate to the intensity of the heat flux due to radiation in the infrared range.	NO				
	Materials and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as molten material must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed the PPE.	NO				
	PPE materials and other components which may be splashed by hot products must also possess sufficient mechanical-impact absorbency (see point 3.1).	NO				
	PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of industrial or fire-fighting equipment must also possess a degree of non-flammability and thermal or arc heat protection corresponding to the risk class associated with the	NO				
3.6.2	Complete PPE ready for use					

	Under the foreseeable conditions of use:	NO				
	(a) the quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold;	NO				
	(b) PPE must, if necessary, prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.	NO				
	If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, the design of such devices must be such that any volatile substances released are discharged beyond the outer protective integument and not towards the user.	NO				
	If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.	NO				

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		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	The manufacturer's instructions accompanying PPE intended for brief use in high-temperature environments must, in particular, provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.	NO				
3.7	**Protection against cold**					
	PPE designed to protect all or a part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is intended.	NO				
3.7.1	***PPE constituent materials and other components***					
	Constituent materials and other components suitable for protection against cold must possess a coefficient of transmission of incident thermal flux as low as required under the foreseeable conditions of use. Flexible materials and other components of PPE intended for use in a low-temperature environment must retain the degree of flexibility required for the necessary gestures and postures.	NO				
	PPE materials and other components which may be splashed by cold products must also possess sufficient mechanical-impact absorbency (see point 3.1).	NO				
3.7.2	***Complete PPE ready for use***					
	Under the foreseeable conditions of use, the following requirements apply:	NO				
	(a) the flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on the part of the body being protected, including the tips of fingers and toes in the case of hands or feet, from attaining, under any circumstances, the pain or health impairment threshold;	NO				
	(b) PPE must as far as possible prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user.	NO				
	If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.	NO				

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	The manufacturer's instructions accompanying PPE intended for brief use in low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment.	NO				
3.8	**Protection against electric shock**					
3.8.1	***Insulating equipment***					
	PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions.	NO				
	To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered in situ is minimised and, in any event, below a maximum conventional permissible value which correlates with the tolerance threshold.	NO				
	Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be under tension must bear markings indicating, in particular, their protection class or corresponding operating voltage, their serial number and their date of manufacture. A space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or NBtions to be conducted.	NO				
	The manufacturer's instructions must indicate, in particular, the exclusive use for which those PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.	NO				
3.8.2	***Conductive equipment***					
	Conductive PPE intended for live working at high voltages shall be designed and manufactured in such a way as to ensure that there is no difference of potential between the user and the installations on which he is intervening.	NO				

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
3.9	**Radiation protection**					
3.9.1	***Non-ionising radiation***					
	PPE designed to prevent acute or chronic eye damage from sources of non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use.	NO				
	To that end, eye protective equipment must be designed and manufactured so as to possess, for each harmful wavelength, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimised and under no circumstances exceeds the maximum permissible exposure value. PPE designed to protect the skin against non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths.	NO				
	Furthermore, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.	NO				
	Glasses suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's instructions must indicate, in particular, how to select the appropriate PPE taking into account the relevant conditions of use such as the distance from the source and the spectral distribution of the energy radiated at that distance.	NO				
	The relevant protection factor number must be marked on all specimens of filtering eye protective equipment by the manufacturer.	NO				
3.9.2	***Ionising radiation***					
3.9.2.1	***Protection against external radioactive contamination***					

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	PPE constituent materials and other components designed to protect all or a part of the body against radioactive dust, gases, liquids or mixtures thereof must be chosen or designed and incorporated so as to ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use.	NO				
	Depending on the nature or condition of these contaminants, the necessary leak-tightness can be provided by the impermeability of the protective integument and/or by any other appropriate means, such as ventilation and pressurisation systems designed to prevent the back-scattering of these contaminants.	NO				
	Any decontamination measures to which PPE is subject must not prejudice its possible reuse during the foreseeable useful life of those types of equipment.	NO				
3.9.2.2	***Protection against external irradiation***					
	PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak electron (e.g. beta) or weak photon (e.g. X, gamma) radiation.	NO				
	The constituent materials and other components of these types of PPE must be chosen or designed and incorporated so as to provide the degree of user protection required by the foreseeable conditions of use without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement (see point 1.3.2).	NO				
	PPE must bear a mark indicating the type and equivalent thickness of the constituent material(s) suitable for the foreseeable conditions of use.	NO				
3.10	**Protection against substances and mixtures which are hazardous to health and against harmful biological agents**					
3.10.1	***Respiratory protection***					
	PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.	YES	EN 149:2001+A1:2009 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 9 / 10			

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.	YES	EN 149:2001+A1:2009 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 9 / 10			
	The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.	YES	EN 149:2001+A1:2009 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 9 / 10			
	The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.	YES	EN 149:2001+A1:2009 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 9 / 10			
	The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.	YES	EN 149:2001+A1:2009 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 9 / 10			
	In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.	YES	EN 149:2001+A1:2009 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 9 / 10			
3.10.2	***Protection against cutaneous and ocular contact***					
	PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.	NO				
	To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.	NO				

4. ESSENTIAL HEALTH & SAFETY REQUIREMENTS – EHSRs (Annex II PPER)

Please choose YES or No for each EHSR. For those you have marked 'yes', please mark an 'X' against the action taken to deal with the requirement. If your action is not test/User Info or marking, please give a brief description under other.

Ref	List of EHSRs as per the PPE Regulation	APPLICABLE	ACTIONS TAKEN TO ADDRESS			
		YES/NO	TESTING Standard/clause	UI Mark X	MARKING Mark X	OTHER (DESCRIBE)
	Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.	NO				
3.11	**Diving equipment**					
	The breathing equipment must make it possible to supply the user with a breathable gaseous mixture, under foreseeable conditions of use and taking account in particular of the maximum depth of immersion.	NO				
	Where the foreseeable conditions of use so require, the diving equipment must comprise the following:	NO				
	(a) a suit which protects the user against cold (see point 3.7) and/or pressure resulting from the depth of immersion (see point 3.2);	NO				
	(b) an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see point 2.8);	NO				
	(c) a lifesaving device enabling the user to return to the surface (see point 3.4.1).	NO				

5. RISK ASSESSMENT

The risk assessment should identify any other risks not already covered by the EHSRs, based on the intended use of the product. Please include a risk assessment statement. If there are no additional risks the statement should confirm this. If there are additional risks, please describe the risk; the action taken may be either testing/user info or marking and you need only mark this with an 'X'. If the action is 'other' please briefly describe the action taken.

PERISTEGRAF have undertaken a risk assessment of the product(s) considering the intended use, and the possibility of mis-use. Our product is Filtering half mask and intended to protect against particles and dust and we have not identified any additional risks, not already addressed by the Essential Health & Safety Requirements of the PPE Regulation.

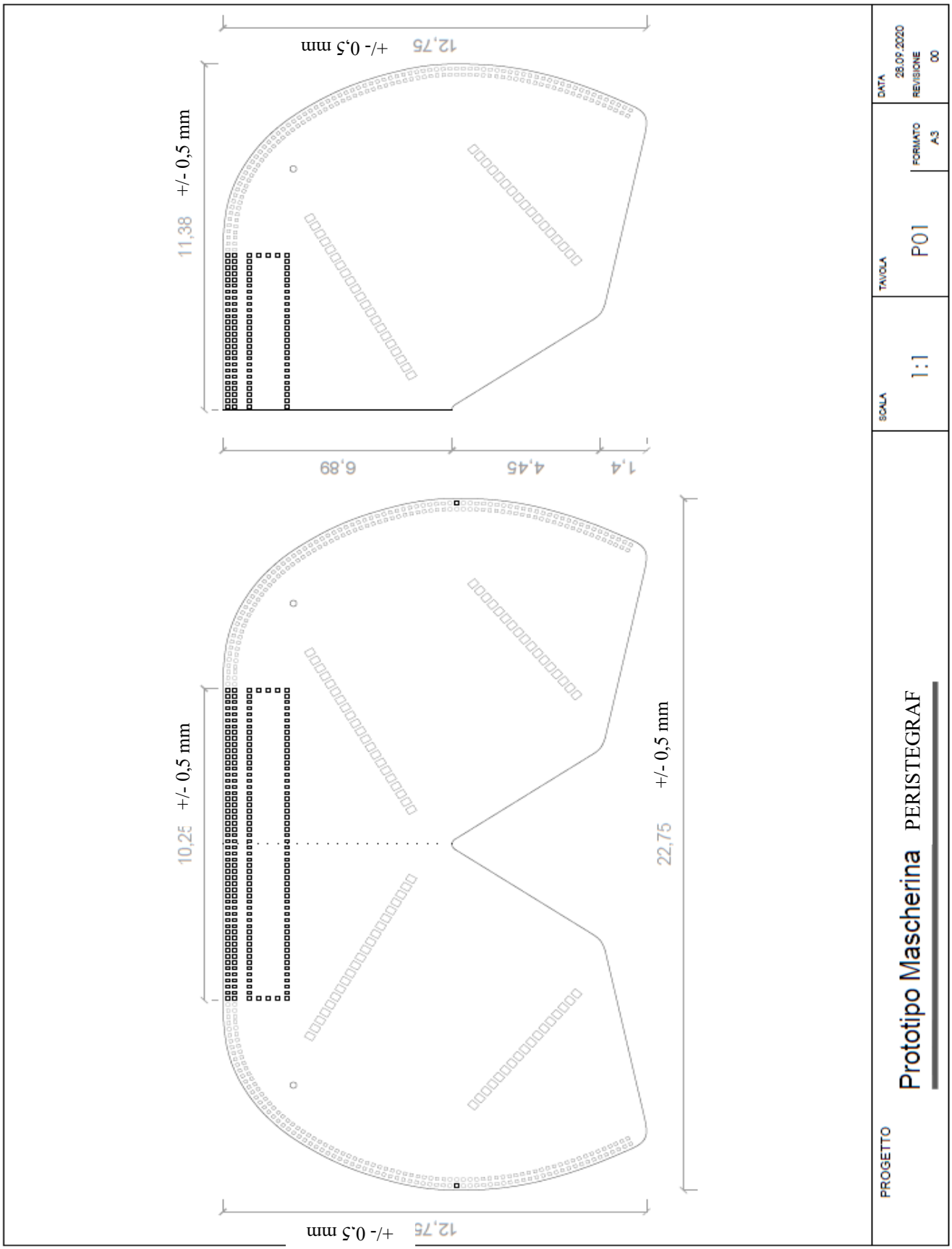
SPECIFIC RISKS	**ACTIONS TAKEN TO ADDRESS (Mark with X)**			
Description of risk	**TEST**	**USER INFO**	**MARKING**	**OTHER (DESCRIBE)**
Particle filtering half-mask is used in an environment with unknown or unauthorized hazardous substances.		Respiratory tract injuries, diseases, increased risk of infection due to loss of the intended protective function of the mask	x	Note on consulting an appropriate safety officer to select the correct mask for the required application in the enclosed instructions for use
Sweating/ Uncomfortable feeling of the user under the particle filtering half mask		Impairment of the wearing comfort of the mask Shifting the pH value of the user's skin	x	Please refer to the enclosed instructions for use for information on how to remove the mask in the event of impairment or discomfort
Too much inward leakage	Performance of laboratory tests according to DIN EN 149:2009-08 to prove that the particle filtering half mask can be used by the user with high probability to protect against the expected possible dangers		x	Respiratory tract injuries, diseases, increased risk of infection due to loss of the intended protective function of the mask
Too high passage of the filter medium	Performing the test of the diffuser according to DIN EN 13274-7:2019-09		x	Respiratory tract injuries, diseases, increased risk of infection due to loss of the intended protective function of the mask
Too tight fit of the particle filtering half mask; high pressure on the user's face		Instructions for use for correct adaptation of the mask to the user's needs and individual head shape in the enclosed instructions for use	x	impairment of mask wearing comfort; injuries and circulatory problems of the user
Particle filtering half mask covers parts of the eye when worn and restricts the user's field of vision	Testing of the visual field according to DIN EN 149:2009-08		x	Restricted field of vision of the user Increase risk of injury

Particle filtering half mask does not close sufficiently to the nose contour, which causes the exhaled air to fog up the vision or (safety) glasses		Instructions for use for correct adaptation of the mask to the user's needs and individual head shape in the enclosed instructions for use	x	Respiratory tract injuries, diseases, increased risk of infection due to loss of the intended protective function of the mask Increased risk of injury due to the limited visibility of the user
Particle filtering half-mask shows function-endangering wear before the end of the normal defined or required service life in the given usage environment	Conditioning of the particle-filtering half-mask through use simulation according to DIN EN 149:2009-08	Respiratory tract injuries, diseases, increased risk of infection due to loss of the intended protective function of the mask	x	
Particle filtering half-mask has burrs or sharp-edged parts that can injure the user during use.	Visual inspection in the final production inspection according to DIN EN 149:2009-08	Injuries in the facial area	x	
Mask no longer ensures adequate air supply after being soaked by rain or water	Conditioning of the particle filtering half mask by means of use simulation according to DIN EN 149:2009-08 Mask is treated with different temperatures and humidity and tested for the fulfillment of its protective function	Lack of oxygen supply Advice to replace soaked masks immediately.	x	
Particle filtering half mask has no or insufficient protective function after being soaked through rain or water	Conditioning of the particle filtering half mask by means of use simulation according to DIN EN 149:2009-08 Mask is treated with different temperatures and humidity and tested for the fulfillment of its protective function	Advice to replace soaked masks immediately.	x	Respiratory tract injuries, diseases, increased risk of infection due to loss of the intended protective function of the mask
Increased breathing resistance after using the particle filtering half mask in a dusty environment		Selection of suitable materials that are resistant to handling and wearing for the time intended for the use of the particle filtering half-mask	x	High breathing resistance can cause the mask to lose its shape when breathing, thus touching mouth and nose. This impairs safety, as the mask may become soaked - insufficient oxygen supply

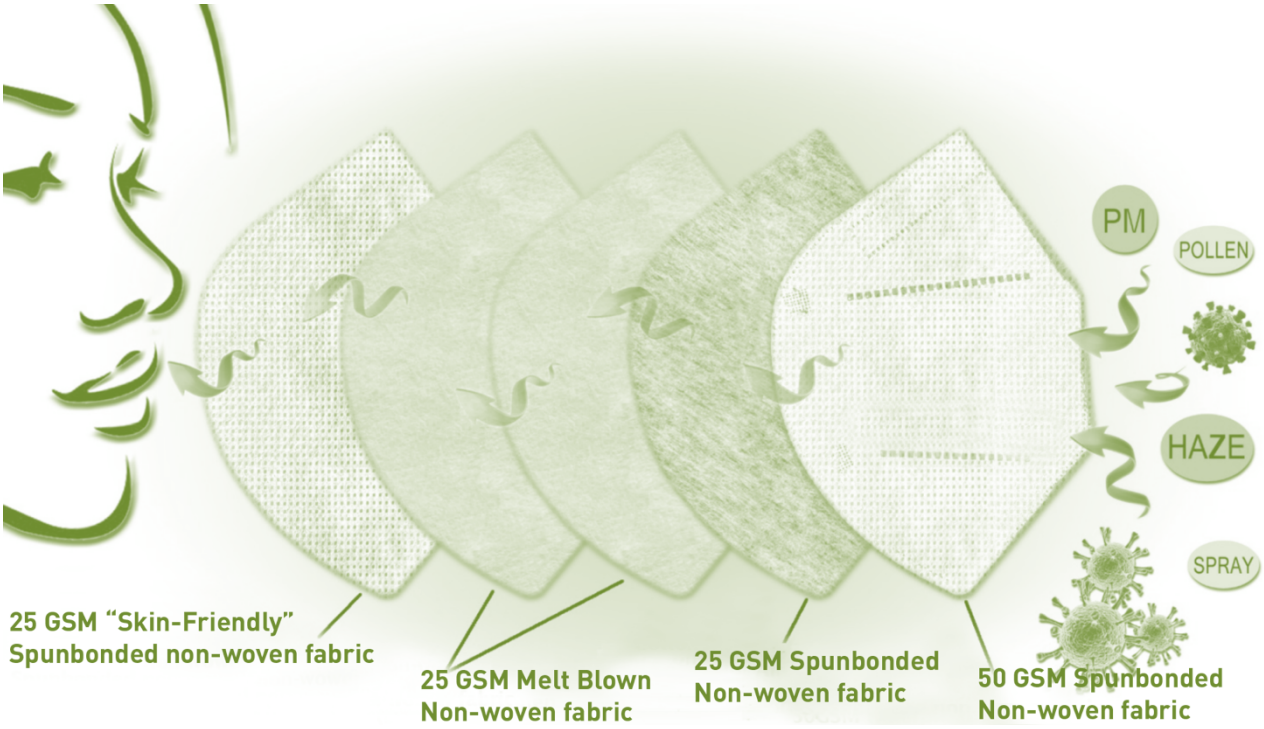
Significantly more difficult breathing when using the particle filtering half mask by users with pre-damaged lung function		Health advice for the use of the particle filtering half mask in case of pre-damaged lung function or breathing difficulties	x	Lack of oxygen supply - impairment of the gas exchange
Particle filtering half mask contains non- flammable filter media in the filter area	Test of flammability of the particle filtering half mask according to DIN EN 149:2009-08		x	Fire hazard / inflammation risk Operator injury risk in the facial area
Mechanical failure of the retaining straps	Conditioning of the particle-filtering half-mask through use simulation according to DIN EN 149:2009-08		x	Respiratory tract injuries, diseases, increased risk of infection due to loss of the intended protective function of the mask
Mechanical failure of the nose clip / missing nose clip	Conditioning of the particle-filtering half-mask through use simulation according to DIN EN 149:2009-08		x	Respiratory tract injuries, diseases, increased risk of infection due to loss of the intended protective function of the mask
Mask is leaking due to material or manufacturing defects (e.g., faulty welding)	Visual inspection in the final production inspection according to DIN EN 149:2009-08		x	Respiratory tract injuries, diseases, increased risk of infection due to loss of the intended protective function of the mask
Insufficient tightness of the particle filtering half mask due to incorrect adaptation to the needs and individual head shape of the user		Instructions on how to perform a face seal check in the enclosed instructions for use	x	Respiratory tract injuries, diseases, increased risk of infection due to loss of the intended protective function of the mask
Danger to the user as a result of materials of the filter medium being entrained by the air flow	Visual inspection in the final production inspection according to DIN EN 149:2009-08		x	Health hazard due to inhalation of entrained materials of the filter medium
Contamination of the mask by reusing the particle filtering half mask after a single use		Respiratory tract injuries, diseases, increased risk of infection due to loss of the intended protective function of the mask	x	Marking of the particle filtering half mask as a disposable product by "NR" on the smallest commercial packaging unit/ on the mask itsel

Contamination due to incorrect deposit/disposal of the particle filtering half mask		Disposal instructions in the enclosed instructions for use / on the mask or packaging Information on how to put on/take off the particle filtering half mask in the instructions for use included in the enclosed instructions for use	x	Respiratory tract injuries, diseases, increased risk of infection due to loss of the intended protective function of the mask
Irritant effect or other negative effect on the health of the user due to existing materials or parts of the particle filtering half-mask	Performance of a skin compatibility test of the particle filtering half mask according to DIN EN 149:2009-08	Skin intolerance Damage to the health of the user	x	Irritant effect or other negative effect on the health of the user due to existing materials or parts of the particle filtering half-mask
Penetration of moisture / damage to the particle filtering half mask during transport or storage		Respiratory tract injuries, diseases, increased risk of infection due to loss of the intended protective function of the mask	x	Information on storage and transport conditions recommended by the manufacturer on the packaging and in the manufacturer's information brochure
Mechanical damage, contamination of the particle filtering half mask		Respiratory tract injuries, diseases, increased risk of infection due to loss of the intended protective function of the mask	x	Implementation of quality assurance measures according to the error catalog final inspection

6. DESIGN AND MANUFACTURING DRAWINGS



7. COMPONENT AND MATERIALS

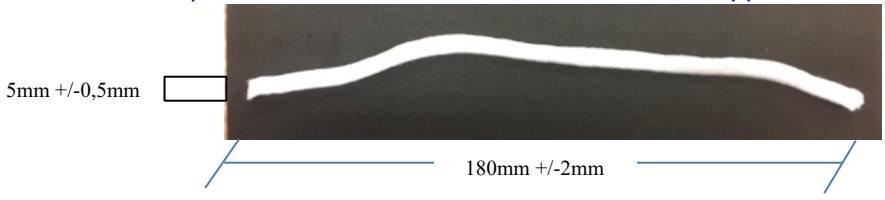


The mask is made of 5 layers, to ensure enhanced performances, composed by the followings (from outside to the face):

- Layer 1 (external) – 50 GSM Spunbonded no-woven fabric, waterproof, providing robustness to the mask such that it does not deforms while breathing. White color.
- Layer 2 – 25 GSM Spunbonded Nonwoven fabric.
- Layer 3 – 25 GSM electrostatic filter of Melt Blown non-woven fabric (1st) filter; it ensures a barrier no less than 95% of bacteria. White color.
- Layer 4 – 25 GSM electrostatic Melt Blown (2nd) filter; combined with the 1sy filtering layer it ensures a barrier to particulates up to almost 99%. White color.
- Layer 5 (internal) – 25 GSM Spunbonded "skin friendly" waterproof fabric, for a perfect and hypoallergenic seal on the face. It does not cause irritation or any other adverse effect to health. White color.

In addition to the 5 layers of fabric, other components of the mask are:

- Elastic Ears' Loop made of 100% spandex yarn, white, meeting the human-ecologic requirements of the STANDARD 100 by OEKO-TEX® presently established in Annex 6 for baby articles. The saucer shape ensures that the skin around the ears is supported without any discomfort.



- Nose Bar – made by PE, PP, Galvanized Wire (composed by White jacket and 2 Silvery metal wires), for ergonomic and comfortable wearing.
-

COMPONENT OR SUB-COMPONENT	MATERIAL	GRADE	EXTERNALLY SOURCED
Nose Bar	80%PE/20%steel anallercic	90mmx0,5 （±1mm）	Made Consulting srl
Ear Loop white /black	80% Polyamide 20% Latex	200mm (±15mm); width= 5mm.	Treccificio Gamba srl- Giorgino silvano filati
Skin care fabric (internal Layer) white/ balck	Spunbonded Non-woven fabric	25gsm （±2.5gsm） 30gsm (±2.5gsm)	Nontex Spa- ESSETEX SRL
Melt blown cloth filter layer 2 x filtering layers	Melt blown cloth	25gsm （±2.5gsm）	Fare Spa
Waterproof fabric (external Layer) White/ black	Spunbonded Non-woven fabric	50gsm （±2.5gsm）	Nontex Spa - Essetex srl

MATERIAL DECLARATION

The material and parts named above, including any of their possible decomposition products, are not known to cause adverse effects to user hygiene or health, nor are likely to cause irritation, during normal use.

NAME: Antonio Boccia	DATE: 22/10/2020

MARK 'X' INSIDE THE BOX TO CONFIRM THE DECLARATION IS TRUE AND VALID ☒

7.1 PRODUCT TO BE FITTED TO ANOTHER MANUFACTURER'S PRODUCT

This section is applicable if your product is designed to be used with another manufacturer's product, e.g. a helmet-mounted earmuff. In this case, you will need to provide evidence that you have an agreement with the applicable manufacturer(s) to use their product during testing, and that they will advise of any design changes to their products, or any issues with production, e.g. product recalls.

Attachments listed below should be sent with the completed technical file

Does your product rely on another manufacturers product to be used as a complete PPE?	YES	
MANUFACTURER NAME	**DOCUMENT TITLE & ISSUE/REVISION STATUS**	**ATTACHED?**
PERISTEGRAF SRL	AGREEMENT FOR SELLER EU	yes

7.2 SPARE PARTS & ACCESSORIES *This section is applicable if you supply spare and accessories for the certified product. Please list the part and confirm the type, and where the spare part of accessory is listed. If spare parts and accessories are listed on a separate sheet to the user information, the sheet should be supplied with the technical file.*		
Does your product have spare parts or accessories available?	NO	
DESCRIPTION	**TYPE?**	**DETAILED IN?**

8. USER INFORMATION DOCUMENT

Please refer to attached Exhibit 02a,b and c for User Instructions translated in Italian, French and German

PERISTEGRAF srl
industria arti grafiche

USER INSTRUCTIONS

MAKE SURE YOU HANDS ARE CLEAN AND SANITIZED BEFORE HANDLING THE MASK

1) Open the mask with the nose clip at the top and flat it, then pull the ear loops.
2) Hold the mask under your chin and then lift to cover your mouth and nose.
3) Pull the rings behind the ears with both hands and adjust for the best comfort.
4) Using both hands, adjust the shape of the nose pad so that it fits the shape of your nose for the best fit (do not do this with one hand! This will affect the seal of the mask).
5) Press the mask onto your face and exhale vigorously. If air escapes from anywhere on the perimeter of the mask, readjust until proper sealing is achieved.

NOTE: The mask can be used for one working shift or multiple times in different days up to 8 hrs in total; in the latter make sure it is stored in a sealed bag and donning and undressing are always performed with clean and sanitized hands.

WARNINGS

- NOT for medical use
- NOT for kids below 10 years old
- NOT for usage in environments where oxygen concentration is below 17 %
- NOT for use in toxic gas environment
- NOT to use with beards or any other facial hairs that interfere with direct touch between the mask and your face skin; carefully shave your face!

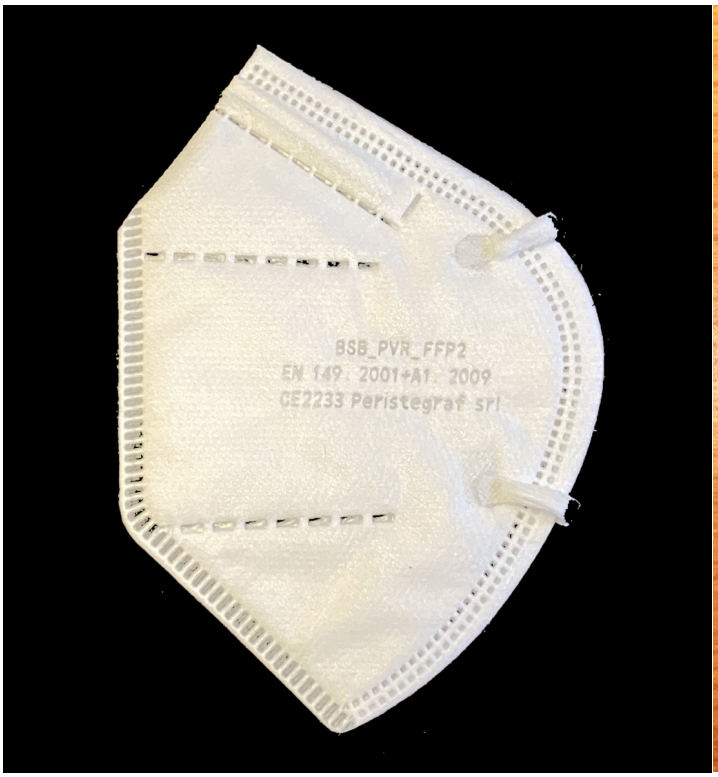
MADE IN ITALY

by PERISTEGRAF SRL Via Giacomo Peroni,150 – 00131

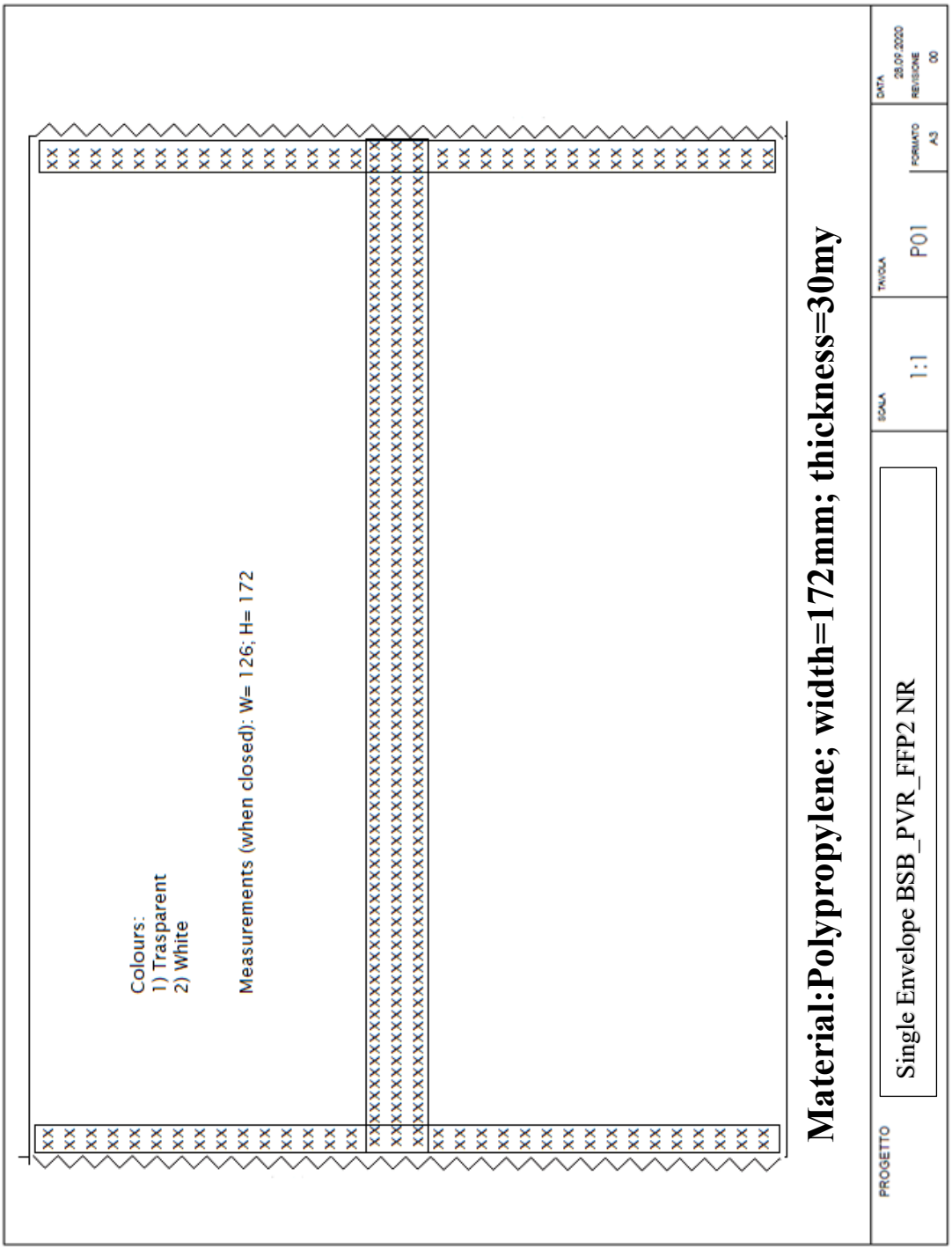
8.1 DECLARATION – MATERIALS FOR MAINTENANCE, CLEANING AND DISINFECTING We declare that the products/materials recommended for maintenance, cleaning and disinfecting do not have any adverse effect on the PPE or the user when applied in accordance with the relevant instructions.
MARK 'X' INSIDE THE BOX TO CONFIRM THE DECLARATION IS TRUE AND VALID ☐

8.2 DECLARATION – SUPPLY OF USER INFORMATION We declare that the user information accompanies each smallest commercially available unit.
MARK 'X' INSIDE THE BOX TO CONFIRM THE DECLARATION IS TRUE AND VALID ☒

9. PRODUCT MARKING



9.1 PACKAGING MARKING



NOTE: This envelope is supposed to contain one single Mask.
Each envelope has a rear label with the User Instructions as per Par. 8

10. EU DECLARATION OF CONFORMITY

PERISTEGRAF srl
industria arti grafiche

EU DECLARATIO OF CONFORMITY

PERISTEGRAF S.R.L.- VIA GIACOMO PERONI,150 - 00131 ROMA - ITALY - TEL. 06-96035140.

FAX. 06-96036338 P.IVA 01768221002

Declare under our sole responsability, that the product below:

Description of the product: **no-valve FFP2 Foldable Respirator/Half Face/Non-Reusable**

Brand name: **BSB_PVR _FFP2 NR**

Model name: **BSB_PVR _FFP2 NR**

Meets the following European regulation:

- 2016/425 (UE) Regulation

CE

Applicable harmonized standard:

- EN 149:2001+A1:2009

The notified body **GEPTESZT KFT. (No. 2233)**
1037 Budapest, Jablonka u. 79
Hungary

Performed the EU type-examination (Module B) and iussed the EU type-examination certificate:
No. 000000

The PPE is subject to the following conformity assesment procedure:

◊ *Conformity to tape based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body:* **GEPTESZT KFT. (No.2233)**

Rome, 22/10/2020

Signed for and on behailf of Peristegraf srl
Antonio Boccia

Peristegraf srl
Via Giacomo Peroni 130 - 00131 Roma
Tel. 06 96035140 - Fax 06 96036338
P.iva 01768221002 - c.f. 07404600582

DOC#: **SS-TF001.01**	**Rev: 01**	PPE: **Half-Mask FFP2**	Date: 18/10/2020

11. TEST REPORTS FOR TYPE EXAMINATION *Each test report used for certification should be listed and attached here.* ***Attachments listed below should be sent with the completed technical file***		
TEST REPORT NUMBER	**TEST HOUSE NAME**	**ATTACHED?**

Prior to perform the complete testing against the EN 149, nine samples of the SUSPIRE respirators have been submitted to a **preliminary test** performed by and accredited laboratory in Italy (Biochem, part of ACCREDIA) www.biochem-bcm.com
Here is a recap pf the result of the test:

- Average particles filtering capacity 98.30%
- Highest capacity found: 98.70%
- Classification of the device: FFP2

A copy of the Test Results is available and attached to this document as **Exhibit 01**

EXHIBIT 01a – Test Result of BFE (2 pages)

ANALISI CHIMICO-FISICHE
MICROBIOLOGICHE
BIOCOMPATIBILITA'
CONSULENZA TECNICA
BIOTECNOLOGIE

Spettabile
PERISTEGRAF S.R.L.
Via Giacomo Peroni, 130
00131 ROMA

Zola Predosa, 29/05/2020

Rif. Vs. ordine del 2020

Rapporto di Prova N°20-0625-01

DETERMINAZIONE DELLA EFFICIENZA DI FILTRAZIONE BATTERICA (BFE)

Descrizione campione

Denominazione: BSB_PVR_FFP2
Codice: BSB_PVR_FFP2
Lotto:
Sterilizzazione: No
Numero di ricevimento: 16145
Data di ricevimento: 21/05/2020
Campionamento effettuato da: PERISTEGRAF S.R.L.

Ulteriori informazioni sul campione

Numero di campioni testati: 5
Dimensioni dell'area dei provini: 50 cm2
Lato del campione a contatto con l'aerosol: La parte interna

Prova iniziata il 26-05-2020 e terminata il 27-05-2020

Metodo di prova

EN 14683:2019 Annex B

Apparecchiature e reagenti

Vacuum pump "GEO Air Plus"
Andersen Cascade Impactor "TE-20-830" modificato
Nebulizzatore MMAD 3,0 ± 0,3 μm
Piastre contenenti TSA

Sommario del metodo

Un controllo negativo viene eseguito facendo passare l'aria, senza aggiunta della soluzione batterica, attraverso il cascade impactor per 2 minuti.

Quindi la soluzione batterica di *Staphylococcus Aureus ATCC 6538*, con una concentrazione da 1,7 x 10^3 a 3,2 x 10^3 UFC/ml, viene immessa nella camera di nebulizzazione.
Viene eseguito un primo controllo positivo, facendo passare la soluzione batterica nebulizzata attraverso il cascade impactor ad un flusso di 28,3 ± 0,5 l/min per 1 minuto. Il flusso d'aria viene mantenuto attraverso il cascade impactor per un ulteriore minuto, per un tempo totale di prova di 2 minuti.
Le piastre dei controlli vengono rimosse dal cascade impactor e vengono posizionate delle nuove piastre per eseguire la prova sui campioni da testare.

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Il provino viene bloccato in posizione tra il primo piatto del cascade impactor ed il cono di ingresso del collettore della nebulizzazione e la procedura utilizzata precedentemente per il controllo positivo viene ripetuta per ognuno dei 5 provini.
Dopo che l'ultimo provino è stato testato, viene eseguita un'ulteriore prova di controllo positivo.
Quindi tutte le piastre vengono incubate a 37±2°C per un periodo di tempo compreso tra le 24 e le 72 ore.
Dopo l'incubazione, per ogni provino e per ogni controllo, si conta il numero di colonie in modo da ottenere, per ciascuno di essi, il numero totale di CFU raccolte dal cascade impactor.
L'efficienza di filtrazione batterica (BFE) viene calcolata per ogni campione, in percentuale, utilizzando la seguente formula:

$$BFE = [(C - T) / C] \times 100$$

dove

C è la media dei conteggi totali delle piastre per le due prove di controllo positivo
T è il conteggio totale delle piastre per il campione in prova

Risultati

Determinazione	Ufc raccolte	BFE (%)	BFE (%) Limite Tipo I	Conformità a Limite Tipo I	BFE (%) Limite Tipo II e IIR	Conformità a Limite Tipo II e IIR
Controllo negativo	0.0					
Controllo positivo 1	2665.0					
Controllo positivo 2	2676.0					
Media controllo positivo	2670.5					
Test 1	34.0	98.7	≥ 95	Conforme	≥ 98	Conforme
Test 2	48.0	98.2	≥ 95	Conforme	≥ 98	Conforme
Test 3	42.0	98.4	≥ 95	Conforme	≥ 98	Conforme
Test 4	55.0	97.9	≥ 95	Conforme	≥ 98	Non conforme
Test 5	51.0	98.1	≥ 95	Conforme	≥ 98	Conforme
Media campione	**46.0**	**98.3**	≥ 95	Conforme	≥ 98	Conforme

NOTE:

Il presente Rapporto di Prova è riferito esclusivamente al campione esaminato.
Nel caso in cui il campione sia stato fornito dal Cliente, i risultati si applicano al campione così come ricevuto.
Il presente Rapporto di Prova non può essere riprodotto parzialmente, salvo approvazione scritta di Biochem.

(#) Dati forniti dal Cliente. Il laboratorio declina la responsabilità di tali dati.

Prova verificata da: Buriani Giampaolo, PhD.

Emissione autorizzata da:
Responsabile del Laboratorio Ing. Giovanni Bassini

FINE RAPPORTO DI PROVA

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EXHIBIT 02a – User Instruction in Italian language

MASCHERA FACCIALE FFP2 NR

ISTRUZIONI PER L'USO

ASSICURATEVI CHE LE VOSTRE MANI SIANO PULITE E SANIFICATE PRIMA DI MANEGGIARE LA MASCHERA

1) Aprire la maschera con la clip per il naso in alto e appiattirla, quindi tirare i passanti per le orecchie.
2) Tenere la maschera sotto il mento e poi sollevarla per coprire la bocca e il naso.
3) Tirare gli elastici dietro le orecchie con entrambe le mani e regolarli per il miglior comfort.
4) Con entrambe le mani, regolare la forma del nasello in modo che si adatti alla forma del vostro naso per la migliore aderenza (non farlo con una mano sola! Questo influirà sulla tenuta della maschera).

Premete la maschera sul viso ed espirate vigorosamente. Se l'aria fuoriesce da qualsiasi punto del perimetro della maschera, regolare nuovamente fino a quando non si ottiene una tenuta adeguata.

NOTA: la maschera può essere utilizzata per un turno di lavoro o più volte in giorni diversi fino a 8 ore in totale; in quest'ultimo caso assicurarsi che sia conservata in un sacchetto sigillato e che la vestizione e lo svestimento siano sempre eseguiti con mani pulite e igienizzate.

AVVERTENZE:

- NON per uso medicale
- NON adatto a bambini sotto i 10 anni
- NON utilizzabile in ambienti con concentrazione di ossigeno inferiore al 17 %
- NON utilizzabile in ambienti con presenza di gas tossici
- NON utilizzare con la barba lunga o altri peli facciali che interferiscono con il contatto diretto tra la maschera e la pelle del viso. Radersi accuratamente!

PRODOTTO IN ITALIA

da PERISTEGRAF SRL Via Giacomo Peroni,150 – 00131 Roma

EXHIBIT 02b – User Instruction in French language

RESPIRATEUR JETABLE FFP2 NR

INSTRUCTIONS D'UTILISATION

ASSUREZ-VOUS QUE VOS MAINS SONT PROPRES ET DÉSINFECTÉES AVANT DE TOUCHER LE MASQUE

1) Posez le masque avec le clip nasal en haut et aplatissez-le, puis tirez sur les élastiques pour les placer derrière les oreilles.
2) Tenez le masque sous votre menton, puis soulevez-le pour couvrir votre bouche et votre nez.
3) Tirez les élastiques derrière les oreilles avec les deux mains et ajustez pour le meilleur confort.
4) A l'aide des deux mains, ajustez la forme de la languette nasale afin qu'elle épouse la forme de votre nez pour un meilleur ajustement (ne le faites pas d'une seule main ! Cela affectera l'étanchéité du masque).
5) Appuyez le masque sur votre visage et expirez vigoureusement. Si de l'air s'échappe de n'importe où sur le périmètre du masque, réajustez jusqu'à ce que l'étanchéité soit obtenue.

REMARQUE : Le masque peut être utilisé pour un shift de travail ou plusieurs fois sur différents jours jusqu'à 8 heures au total ; assurez-vous toujours qu'il soit stocké dans un sac scellé et que toute manipulation soit toujours effectuée avec des mains propres et désinfectées.

AVERTISSEMENTS :

- PAS pour usage medical
- PAS pour les enfants de moins de 10 ans
- NE PAS utiliser dans des environnements où la concentration d'oxygène est inférieure à 17%
- NE PAS utiliser dans un environnement de gaz toxiques
- NE PAS utiliser avec la barbe ou tout autre chose sur le visage qui interfère avec le contact direct entre le masque et la peau ; rasez-vous soigneusement

PRODUIT EN ITALIE De PERISTEGRAF SRL
Via Giacomo Peroni, 150-00131 Rome (RM)

EXHIBIT 02c – User Instruction in German language

PERISTEGRAF srl
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ATEMSCHUTZGERAT FFP2 NR

GEBRAUCHSEINWEISUNG

STELLEN SIE SICHER, DASS IHRE HÄNDE SAUBER UND DESINFIZIERT SIND, BEVOR SIE DIE MASKE ANFASSEN

1) Öffnen Sie die Maske mit dem Nasenbügel nach oben und legen Sie sie flach, ziehen Sie dann an den Ohrschlaufen
2) Halten Sie die Maske unter Ihr Kinn und heben Sie sie dann an, um Ihren Mund und Ihre Nase zu bedecken
3) Ziehen Sie die Ringe mit beiden Händen hinter die Ohren und stellen Sie sie für den besten Komfort ein.
4) Stellen Sie mit beiden Händen die Form des Nasenpolsters so ein, dass es sich der Form Ihrer Nase optimal anpasst (nicht mit einer Hand! Dies beeinträchtigt die Abdichtung der Maske).
5) Drücken Sie die Maske auf Ihr Gesicht und atmen Sie kräftig aus. Wenn an irgendeiner Stelle am Umfang der Maske Luft austritt, passen Sie die Maske wieder an, bis sie richtig abgedichtet ist.

ANMERKUNG: Die Maske kann für eine Arbeitsschicht oder mehrmals an verschiedenen Tagen bis zu insgesamt 8 Stunden verwendet werden; bei letzterem ist darauf zu achten, dass sie in einem versiegelten Beutel aufbewahrt wird und das An- und Ausziehen immer mit sauberen und desinfizierten Händen erfolgt

WARNUNGEN:

- o NICHT für medizinischen Gebrauch
- o NICHT für Kinder unter 10 Jahren
- o NICHT zur Verwendung in Umgebungen, in denen die Sauerstoffkonzentration unter 17 % liegt
- o NICHT zur Verwendung in einer Umgebung mit toxischen Gasen
- o NICHT mit Bärten oder anderen Gesichtshaaren verwenden, die den direkten Kontakt zwischen der Maske und Ihrer Gesichtshaut stören; rasieren Sie Ihr Gesicht sorgfältig!

IN ITALIEN HERGESTELLT von PERISTEGRAF SRL Via Giacomo Peroni, 150 - 00131 Rom (RM)

EXHIBIT 03 – Production FLOW CHART