DISTRIBUZIONE JUNIOR SRL

VIA PACE, 25/6 - 80047 SAN GIUSEPPE VESUVIANO (NA) - ITALY

Particulate Respirator CE TD

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Content

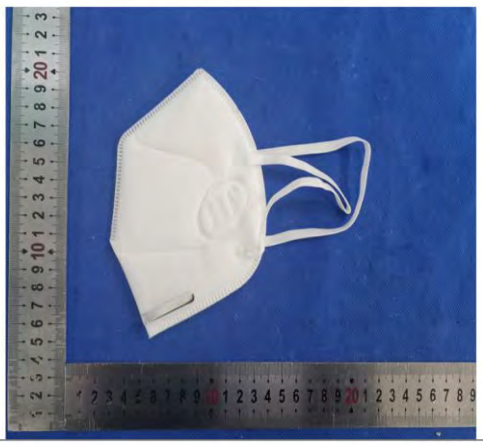
01 Company Information

Name of Applicant	DISTRIBUZIONE JUNIOR SRL
Address	VIA PACE, 25/6 -80047 SAN GIUSEPPE VESUVIANO (NA) -ITALY
Contact(s)	LUIGI APRILE
Position	GENERAL MANAGER
Telephone Number	+39 0813626381
Fax Number	+39 0813626381
Email address	info@enhanceorthodontics.it

Manufactured:

MEIZHUANGCHEN Health Technology (Shenzhen) Co., Ltd
MEIZHUANGCHEN Industrial Park, 12 Yuhe Road, Baoan District, Shenzhen

02 Product Details

Product Name	Particulate Respirator
Product Introduction	The particulate respirator is made of non-woven fabric, melt-blown fabric, hot air cotton, nose clip, mask belt, which can protect against certain particles, such as dust, smoke and fog.
Intended Use	This respirator helps protect against certain particles, such as dust, smoke and fog.
Classification	III, PPE 2016/425
Photographs of the product	Photo 1 view ☒ front ☐ back ☐ side ☐ top ☐ internal ☐ bottom  Photo 2 view ☐ front ☒ back ☐ side ☐ top ☐ internal ☐ bottom 

03 Risk Assessment

Assessment of potential risks associated with the use of this equipment:

This respirator helps protect against certain particles, such as dust, smoke and fog. According to the different protection requirements, choose the particulate respirator corresponding to the filter level.

The risks related to the use of his PPE in the foreseeable conditions of use:

Risk type	potential risk	formation factors	controlled measure
Risks related to product use	may result in the equipment failing to adequately protect the user, resulting in serious respiratory harm.	Not paying attention to the protection level on the label	Standardize product label
		without appropriate wearing according to the instruction	detailed use method, necessary warning instructions and specification
		failure to follow the warning of single use of the mask	hazard warning and specification for reuse of disposable products
		Improper storage beyond the service life	Stored conditions in the user instruction
		The users did not check the product before use	Add the warnings in the IFU
		Use the product in atmospheres containing less than 19.5 percent oxygen or the condition dangerous to life or health	Add the warnings in the IFU
		facial beard, hair or other conditions affect the fit of face and mask	Add the warnings in the IFU
Risks caused by functional failure	Improper product packaging, package damage, impact on product protection function	Package damage during production, transportation, handling and storage; The packing seal is not tight; Improper selection of packaging materials	Strictly control the packaging process
	loss of product integrity and ineffective protection	The parts of the product are not sewn and bonded tightly or the material itself is damaged to meet the isolation requirements	Strictly control production process and product inspection
Risks to the environment	Environmental pollution	Contaminated products in storage and transportation	Strictly control product storage and

			transportation

04 Essential Health and Safety Requirements

In accordance with Regulation (EU) 2016/425 - Annex II

Clause	REQUIREMENT	CONFORMITY
1	**General requirements applicable to all PPE**	
	PPE must provide adequate protection against the risks against which it is intended to protect.	Regulation 2016/425
1.1	**Design principles**	
1.1.1	**Ergonomics** PPE must be so designed and manufactured 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 possible level.	EN 149:2001+A1:2009 Clause 4, 7.13, 8.4.1
1.1.2	**Levels and classes of protection**	
1.1.2.1	**Highest level of protection possible** 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 of normal performance of the activity.	EN 149:2001+A1:2009 Clause 5
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.	EN 149:2001+A1:2009 Clause 5
1.2	**Innocuousness of PPE**	
1.2.1	**Absence of risks and other 'inherent' nuisance factors** PPE must be so designed and manufactured as to not to creat risks and other nuisance factors under foreseeable conditions of use.	EN 149:2001+A1:2009 Clause 7.5, 7.10
1.2.1.1	**Suitable constituent materials** PPE materials and parts, including any of their decomposition products, must not adversely affect hygiene or health.	EN 149:2001+A1:2009 Clause 7.5, 7.8, 7.10, 8.2, 8.4, 8.5
1.2.1.2	**Satisfactory surface conditions of all PPE parts in contact with the User** Any PPE part in contact or in potential contact with the user when such equipment is worn must be free of roughness, sharp edges, projections and the like which would cause excessive irritation or injuries.	EN 149:2001+A1:2009 Clause 7.5, 7.8, 7.10
1.2.1.3	**Maximum permissible user impediment** Any impediment caused by PPE to the actions to be carried out, postures to be adopted and sensory perception must be minimised; nor must PPE cause movements which endanger the user or other persons.	EN 149:2001+A1:2009 Clause 7.5, 7.8, 7.13, 7.14
1.3	**Comfort and effectiveness**	

Clause	REQUIREMENT	CONFORMITY
1.3.1	**Adaptation of PPE to user morphology** PPE must be so designed and manufactured as to facilitate 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 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 size range.	EN 149:2001+A1:2009 Clause 4, 7.13, 7.18, 8.4.1
1.3.2	**Lightness and design strength** PPE must be as light as possible without prejudicing design strength and efficiency. Apart from specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding, environmental factors in the foreseeable conditions of use.	EN 149:2001+A1:2009 Clause 4, 7.13, 7.18
1.3.3	**Compatibility of different classes or types of PPE designed for simultaneous use** If the same manufacturer markets several PPE models of different classes or types in order to ensure the simultaneous protection of adjacent parts of the body against combined risks, these must be compatible.	Not applicable
1.3.4	**Protective clothing containing removable protectors** Protective clothing containing removable protectors constitutes PPE and shall be assessed as a combination during conformity assessment procedures.	Not applicable
1.4	Manufacturer's instructions and Informations In addition to the name and address of the manufacturer and/or his authorised representative established in the Community, the notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on: (a) Instructions for storage, use, cleaning, maintenance, servicing and disinfecting. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions; (b) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question; (c) Where applicable, suitable accessories that may be used with the PPE and the characteristics of appropriate spare parts; (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;	EN149:2001+A1:2009 Clause 7.4, 9.1, 10.1, 10.2, 10.3, 10.4, 10.5, 10.6, 10.7 Refer to User Instruction

Clause	REQUIREMENT	CONFORMITY
	(g) The significance of any markings (see 2.12) (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. 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.	
2	**Additional Requirements Common to Several Types of PPE**	
2.1	**PPE incorporating adjustment systems** If PPE incorporates adjustment systems, the latter must be so designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.	Not applicable
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.	EN 149:2001+A1:2009 Clause 7.5, 7.8
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. 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. If necessary, such PPE must be treated or provided with means to prevent misting-up. Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.	EN 149:2001+A1:2009 Clause 7.14, 8.4.1
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.	EN 149:2001+A1:2009 Clause 7.4, 8.3, 8.5, 9 Refer to User Instruction

Clause	REQUIREMENT	CONFORMITY
	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. 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 inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.	
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.	EN 149:2001+A1:2009 Clause 4, 7.13, 7.18
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.	Not applicable.
2.7	**PPE intended for rapid intervention or to be put on 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. 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.	EN149:2001+A1:2009 Clause 7.13
2.8	**PPE for intervention in very dangerous situations** 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. 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. 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.	EN149:2001+A1:2009 Clause 7.13, 7.18, 9.1, 10.1, 10.2, 10.3, 10.4, 10.5, 10.6, 10.7 Refer to User Instruction

Clause	REQUIREMENT	CONFORMITY
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.	EN149:2001+A1:2009 Clause 7.8, 7.13 Refer to User Instruction
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.	Not applicable. The item is not designed for connection to another
2.11	**PPE incorporating a fluid circulating 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.	Not applicable. The item does not incorporate a fluid circulation system
2.12	**PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety** 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 harmonised 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. 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.	EN 149:2001+A1:2009 Clause 9.0, 10.0 Refer to User Instruction
2.13	**PPE capable of signalling the user's 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.	Not applicable.
2.14	**Multi-risk PPE** PPE intended to protect the user against several potentially simultaneous	Not applicable. The item is not designed to protect the

Clause	REQUIREMENT	CONFORMITY
	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.	user against multi-risks
3	**Additional Requirements Specific to Particular Risks**	
3.1	**Protection against mechanical impact**	
3.1.1	**Impact caused by falling or ejected objects and collision of parts of the body with an obstacle** 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.	Not applicable.
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.	Not applicable
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. Such PPE must also ensure that, after braking, the user is maintained in a correct position in which he may await help if necessary. The manufacturer's instructions must specify, in particular, all relevant information relating to: (a) the characteristics required for the reliable external anchorage point and the necessary minimum clearance below the user; (b) the proper way of putting on the body harness and of attaching the connexion system to the reliable external anchorage point.	Not applicable
3.1.3	**Mechanical vibration** 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 risks.	Not applicable

Clause	REQUIREMENT	CONFORMITY
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.	Not applicable
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.	Not applicable
3.4	**Prevention 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. PPE may be wholly or partially inherently buoyant or may be inflated by gas which can be manually or automatically released, or inflated orally. Under the foreseeable conditions of use: (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; (b) inflatable PPE must be capable of inflating rapidly and fully. Where particular foreseeable conditions of use so require, certain types of PPE must also satisfy one or more of the following additional requirements: (a) they must have all the inflation devices referred to in the second subparagraph, and/or a light or sound-signalling device; (b) they must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium; (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.	Not applicable
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	Not applicable

Clause	REQUIREMENT	CONFORMITY
	particular, to swim or take action to escape from danger or to rescue other persons.	
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)]. 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.	Not applicable
3.6	**Protection against heat and/or fire** PPE designed to protect all or 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.	Not applicable
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. 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. 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. PPE materials and other components which may be splashed by hot products must also possess sufficient mechanical-impact absorbency (see point 3.1). 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 foreseeable conditions of use. They must not melt when exposed to flames nor contribute to flame propagation.	Not applicable
3.6.2	**Complete PPE ready for use** Under the foreseeable conditions of use: (a) the quantity of heat transmitted by PPE to the user must be sufficiently	EN 149:2001+A1:2009 Clause 7.12, 7.16con

Clause	REQUIREMENT	CONFORMITY
	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; (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. If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, their design must be such that any volatile substances released are discharged beyond the outer protective integument and not towards the user. If PPE incorporates a breathing device, the latter must adequately fulfil the protective function assigned to it under the foreseeable conditions of use. 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.	
3.7	**Protection against cold** PPE designed to protect all or 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.	Not applicable.
3.7.1	**PPE constituent materials and other components** Constituent materials and other components suitable for protection against cold must posses a coefficient of transmission if 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. PPE materials and other components which may be splashed by cold products must also possess sufficient mechanical-impact absorbency (see point 3.1)	Not applicable.
3.7.2	**Complete PPE ready for use** Under the foreseeable conditions of use, the following requirements apply: (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; (b) PPE must as far as possible prevent the penetration of such liquids as	Not applicable

Clause	REQUIREMENT	CONFORMITY
	rain water and must not cause injuries resulting from contact between its cold protective integument and the user. If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use. 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.	
3.8	**Protection against electric shock**	Not applicable
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. 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. 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 inspections to be conducted. 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.	Not applicable
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.	Not applicable
3.9	**Radiation protection**	

Clause	REQUIREMENT	CONFORMITY
3.9.1	**Non-Ionising radiation** 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. 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. 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. 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. The relevant protection factor number must be marked on all specimens of filtering eye protective equipment by the manufacturer.	Not applicable
3.9.2	**Ionising radiation**	
3.9.2.1	**Protection against external radioactive contamination** PPE constituent materials and other components designed to protect all or part of the body against radioactive dust, gases, liquids or mixtures thereof must be so chosen or designed and incorporated as to ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use. 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 pressurization systems designed to prevent the back-scattering of these contaminants. Any decontamination measures to which PPE is subject must not prejudice its possible re-use during the foreseeable useful life of these classes of	Not applicable

Clause	REQUIREMENT	CONFORMITY
	equipment.	
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. 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). PPE must bear a mark indicating the type and equivalent thickness of the constituent material(s) suitable for the foreseeable conditions of use.	Not applicable
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. 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. 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. 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. 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. 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.	EN 149:2001+A1:2009 Clause 7.5, 7.8, 7.9, 7.10, 7.11, 7.12, 7.16, 9, 10 Refer to User Instruction

Clause	REQUIREMENT	CONFORMITY
3.10.2	**Protection against cutaneous and ocular contract** 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. 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. 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.	EN 149:2001+A1:2009 Clause 7.5, 7.8, 7.9, 7.10, 7.11, 7.12, 7.16, 9, 10 Refer to User Instruction
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. Where the foreseeable conditions of use so require, the diving equipment must comprise the following: (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); (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); (c) a lifesaving device enabling the user to return to the surface (see point 3.4.1).	Not applicable

05 Equipment Parts List – Materials

S/N	Part name		Material name	Classification of material
1	Mask body	Outer layer	50g non-woven fabric	Raw material
		Middle layer	melt-blown fabric + hot air cotton	
		Inner layer	30g non-woven fabric	
2	Mask belt		Polyamide/Spandex	Raw material
3	Nose clip		Iron plastic wire	Raw material
4	Packing bag		OPP bag	Inner packing material
5	Packing box		white board paper	Middle packing material
6	Carton		Five-layers Corrugated paper container	Outer packing material

06 Test Reports / Supporting documents

6.0 Biological Compatibility Test

The particulate respirator materials have been tested for biological compatibility according to ISO10993-1, the tested items are: Test for in vitro cytotoxicity (MTT cytotoxicity test), Test for in irritation (Animal skin irritation test) and Test for skin sensitization (Closed-patch test).

Conclusions: The results showed that the particulate respirator materials have no cytotoxic potential, significant sensitization and significant irritation. So, the biocompatibility test was complied with the regulation.

6.1 Type Test

The particulate respirator should implement type test according to EN 149:2001+AC:2019. We use the sample of particulate respirator to do the type test. The test results meet the requirement of this standard.

6.2 Physical and chemical properties test

In according with <Control Procedure of monitoring and Measuring>, < Finished product Inspection specification>.

6.2.1 In order to prove the physical and chemical performances of products are qualified, we tested all the physical and chemical properties of particulate respirator before delivery.

6.2.2 Aging test (2 years)

In order to prove that the products in the valid period can still maintain the original quality characteristics, we also tested all the physical and chemical properties of particulate respirator after accelerated aging test.

6.3 Conclusions

The results of all the tests above showed that the test items meet the requirements and ensure that our products can be put into market only if they pass the test both before delivery. Also ensure that the valid period of 2 years and can maintain original quality.

7.1 IFU

07 Instruction for Use

CE 2163

[Product name]: Particulate Respirator

[Product Model]: ENKN95-001

[Product Type]: FFP2 NR001

[Intended use]:

This respirator helps protect against certain particles, such as dust, smoke and fog.

[Performance]:

filter penetration and extended exposure (loading) test - evaluates the filtration performance when new and over time

breathing resistance - evaluates the ease of breathing (inhalation and exhalation) through the respirator

total inward leakage - evaluates the filter penetration, valve leakage (if fitted) and importantly the face seal leakage of the respirator when worn by a panel of different people whilst conducting simulated work exercises.

clogging resistance - evaluates the ability of the respirator to continue to function effectively and provide respiratory protection in very high dust environments.

Reusable products are also subjected to a cleaning cycle (specified by the manufacturer) and 24 hour storage to confirm the product performance is not affected by re-use. Clogging resistance testing is a mandatory requirement for reusable products, but is optional for single shift use only (non reusable) products. A full copy of EN 149:2001+A1:2009 can be purchased from your national standards body.

Marking designations

NR = Non reusable (single shift use only)

D = Meets the clogging resistance requirements

[Warning]:

- ★ Before using the mask, check whether the packaging is intact, and confirm the marked expiration date of the outer package and use it within the expiration date.
- ★ Do not exceed maximum use concentrations established by regulatory standards.
- ★ If the product is not used in this instruction, or is used beyond the use limit, or facial beard, hair or other conditions affect the fit of face and mask, or is worn all the time in the process of contacting with harmful substances, the protection function of the product will be reduced, and disease or even death may be caused.
- ★ Don't use in atmospheres containing less than 19.5 percent oxygen.
- ★ Don't use in atmospheres immediately dangerous to life or health.
- ★ Don't use the equipment in explosive atmosphere.
- ★ As the particle filtering half mask is marked “NR”, it shall not be used for more than one shift.

[Shelf-time]: 2 years

[Instruction of use]:

★ Step 1: Stretch the mask out to check that the front of the mask is intact.

★ Step 2: Cover your Chin with a mask.

★ Step 3: Cover the nose and mouth. Attach the ear band to each ear to make the ear band more comfortable.

★ Step 4: Place the fingertips of two hands at the top of the nose piece. Mould the nose piece to the shape of your nose.

★ Step 5: Over the front of the respirator with both hands. Sharply exhale and inhale. if air leaks around the nose. readjust the nose clip as described in Step4.if air leaks at the respirator edges. work the straps back along the sides if the head to eliminate leakage. Repeat the procedure until the respirator fts property.

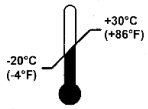
[Storage and transportation]:

It should be stored in a dry, ventilated, non-corrosive gas environment, away from fire sources and flammable materials.

[Transportation Conditions]:

Avoid heavy pressure, direct sunlight and humidity during transportation.

[Symbols]:

	End of shelf life	CE 2163	CE mark and Notified Body No.
	Storage Temperature Range -20°C (-4°F) to +30°C (+86°F).		Do not re-use
	Handle with Care		See information supplied the manufacturer
	Keep away from sunlight		Storage Maximum Relat Humidity <80% RH
	Keep dry		Keep up right duri transport

[Declaration of Conformity]:

The contents of this chapter refer to the latest signed version of chapter 10.

08 Manufacturer's Instructions and Information

Product brief introduction Product

Name: Particulate Respirator

[Product Model]: 1. ENHANCE FFP2

[Product Type]: ENKN95-001

8.1 Life time: 2 years.

The particulate respirator is made of non-woven fabric, melt-blown fabric, hot air cotton, nose clip, mask belt, which can protect against certain particles, such as dust, smoke and fog.

9.1 Production flow chart

The production flow charts of Particulate Respirator include composite molding, finishing process and packaging, the critical process is composite molding.

9.2 Performance data of the product

9.2.1 Performance tests are performed in accordance with EN 149:2001+A1:2009.

9.2.2 Physical and chemical tests are performed to the Particulate Respirator in accordance with <Finished product inspection and test specification>.

9.3 Instruction of use

★ Step 1: Stretch the mask out to check that the front of the mask is intact.

★ Step 2: Cover your Chin with a mask.

★ Step 3: Cover the nose and mouth. Attach the ear band to each ear to make the ear band more comfortable.

★ Step 4: Place the fingertips of two hands at the top of the nose piece. Mould the nose piece to the shape of your nose.

★ Step 5: Over the front of the respirator with both hands. Sharply exhale and inhale. if air leaks around the nose. readjust the nose clip as described in Step4.if air leaks at the respirator edges. work the straps back along the sides if the head to eliminate leakage. Repeat the procedure until the respirator fts property.

9.4 Warning

★ Before using the mask, check whether the packaging is intact, and confirm the marked

expiration date of the outer package and use it within the expiration date.

★ Do not exceed maximum use concentrations established by regulatory standards.

★ If the product is not used in this instruction, or is used beyond the use limit, or facial beard, hair or other conditions affect the fit of face and mask, or is worn all the time in the process of contacting with harmful substances, the protection function of the product will be reduced, and disease or even death may be caused.

★ Don't use in atmospheres containing less than 19.5 percent oxygen.

★ Don't use in atmospheres immediately dangerous to life or health.

★ Don't use the equipment in explosive atmosphere.

★ As the particle filtering half mask is marked “NR”, it shall not be used for more than one shift.

9.5 Storage Conditions

★ It should be stored in a dry, ventilated, non corrosive gas environment, away from fire sources and flammable materials.

9.6 Transportation Conditions

★ Avoid heavy pressure, direct sunlight and humidity during transportation.

09 Declaration of Conformity

EU Declaration of Conformity- this declaration will be translated into a language appropriate to the country destination of the product.

1. ENHANCE FFP2 NR: EN001
2. Name and address of the manufacturer and, where applicable, his authorized representative:

Name of Applicant	DISTRIBUZIONE JUNIOR SRL
Address	VIA PACE, 25/6 -80047 SAN GIUSEPPE VESUVIANO (NA) -ITALY
Contact(s)	LUIGI APRILE
Position	GENERAL MANAGER
Telephone Number	+39 0813626381
Fax Number	+39 0813626381
Email address	info@enhanceorthodontics.it

Company Name: MEIZHUANGCHEN Health T echnology (Shenzhen) Co., Ltd
Company Address: MEIZHUANGCHEN Industrial Park, 12 Yuhe Road, Baoan District, Shenzhen

3. This declaration of conformity is issued under the sole responsibility of the manufacturer:

4. Object of the declaration (identification of PPE allowing traceability; where necessary for the identification of the PPE, a colour image of sufficient clarity may be included):

Mask with CE marking (ENHANCE FFP2 ENKN95-001).

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonization legislation:

PPE Regulation (EU) 2016/425.

6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

EN 149:2001+A1:2009

7. Where applicable, the notified body Universal Certification and Surveillance Service Trade Ltd. Co. NB 2163, Necip Faz#l Bulvar# Keyap Sitesi E2 Blok No: 44/84 Yukar# Dudullu, Ümraniye-Istanbul, Turkey performed the EU type-examination (Module B) and issued the EU type-examination certificate

CE no. see the EU type-examination certificate

8. Where applicable, the PPE is subject to the conformity assessment
is subject to the procedure set out in Module C2/ D of Regulation (EU) 2016/425 Personal Protective Equipment under the supervision of the notified under surveillance of the notified body Universal Certification and Surveillance Service Trade Ltd. Co. NB 2163 Necip Faz#l Bulvar# Keyap Sitesi E2 Blok No: 44/84 Yukar# Dudullu, Ümraniye-Istanbul, Turkey.

9. Additional information:

N/A

Name, Function: LUIGI APRILE – GENERAL MANAGER
Place and date of Issue: SAN GIUSEPPE VESUVIANO (NA) 27.04.2020 Signature: