

**TECHNICAL ASSESSMENT REPORT**

**REPORT DATE / NO :** 08.05.2020 / KKD-2163-667

**Client:** DISTRIBUZIONE JUNIOR SRL

**Centre Address:** Via Pace, 25/26 - 80047 San Giuseppe Vesuviano (Na), ITALY

**Manufacturer:** MEIZHUANGCHEN HEALTH TECHNOLOGY (SHENZHEN) CO., LTD.

**Manufacturing Address:** Meizhuangchen Industrial Park, 12 Yube Road, Shiyao Town, Baoan District, Shenzhen, CHINA

This report is to the above mentioned firm with the NATIONAL PROTECTIVE TESTING LLC firm's 25.04.2020 numbered NPT20040712681 test report and the test results which have been obtained according to the EN 149: 2001 + A1: 2009 standards of the product specified in this report, its relation was evaluated with Essential Requirements of Personal Protective Equipments and the results were found to be appropriate.

This report is an annex and an inseparable part of the EU Type Examination Certificate No. 2163 - PPE - 667 issued to the company. The test results and issued certificate belong only to the tested product. The technical report consists of a total of 7 pages.

**Product Description :** Particle Filtering Half Mask

Total Inward Leakage: Classification – FFP2

**Trademark :** ENHANCE

**Model :** ENKN95-001





THE CLAUSES OF EN 149: 2001 + A1: 2009 STANDARD RELATED TO EUROPEAN UNION DIRECTIVE  
EU 2016/425 REQUIREMENTS

**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.

**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 by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

**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.

**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 preclude risks and other nuisance factors under foreseeable conditions of use.

**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.

**1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user**

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

**1.2.1.3. Maximum permissible user impediment**

Any impediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

**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.

**1.3.2. Lightness and design strength**

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the 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 the effects of ambient phenomena inherent under the foreseeable conditions of use

**1.4. Information supplied by the manufacturer**

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) In addition to the name and address of the manufacturer and/or his authorized representative established in the Community
- b) Storage, use, cleaning, maintenance, servicing and disinfection, cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
- c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;
- d) Suitable PPE accessories and the characteristics of appropriate spare parts;
- e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
- f) The obsolescence deadline or period of obsolescence of PPE or certain of its components;
- g) The type of packaging suitable for transport;
- h) The significance of any markings (see 2.12)
- i) Where appropriate the references of the Directives applied in accordance with Article 5(6) (b);
- j) The name, address and identification number of the notified body involved in the design stage of the PPE

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination

Breathing Resistance : Exhalation					
Condition	No. of Sample	The dummy head position	Flow Rate 160 L/min	Exhalation Resistance	
				Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	29	Facing directly	2,3	FFP1 ≤ 3	Passed
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,1		
		Lying on the left side	2,3		
		Lying on the right side	2,0		
(A.R.)	30	Facing directly	2,2	FFP2 ≤ 3	
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,1		
		Lying on the left side	2,3		
		Lying on the right side	2,2		
Conditioning : (A.R.) As Received, original					
Breathing Resistance : Exhalation					
Condition	No. of Sample	The dummy head position	Flow Rate 160 L/min	Exhalation Resistance	
				Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	31	Facing directly	2,0	FFP1 ≤ 3	Passed
		Facing vertically upwards	2,1		
		Facing vertically downwards	1,9		
		Lying on the left side	2,1		
		Lying on the right side	2,0		
(S.W.)	1	Facing directly	2,2	FFP3 ≤ 3	
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,0		
		Lying on the left side	2,2		
		Lying on the right side	2,0		
Conditioning : (A.R.) As Received, original (S.W.) Simulated wearing treatment					
Breathing Resistance : Exhalation					
Condition	No. of Sample	The dummy head position	Flow Rate 160 L/min	Exhalation Resistance	
				Requirements in accordance with EN 149:2001 + A1:2009	Result
(S.W.)	2	Facing directly	2,1	FFP1 ≤ 3	Passed
		Facing vertically upwards	2,0		
		Facing vertically downwards	2,0		
		Lying on the left side	2,1		
		Lying on the right side	1,9		
(S.W.)	3	Facing directly	2,0	FFP3 ≤ 3	
		Facing vertically upwards	2,3		
		Facing vertically downwards	2,0		
		Lying on the left side	2,1		
		Lying on the right side	2,1		
Conditioning : (S.W.) Simulated wearing treatment					
Breathing Resistance : Exhalation					
Condition	No. of Sample	The dummy head position	Flow Rate 160 L/min	Exhalation Resistance	
				Requirements in accordance with EN 149:2001 + A1:2009	Result
(T.C.)	13	Facing directly	2,0	FFP1 ≤ 3	Passed
		Facing vertically upwards	2,1		
		Facing vertically downwards	1,9		
		Lying on the left side	1,9		
		Lying on the right side	2,0		
(T.C.)	14	Facing directly	2,2	FFP3 ≤ 3	
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,2		
		Lying on the left side	2,2		
		Lying on the right side	2,2		
Conditioning : (T.C.) Temperature Conditioning					

Article	Breathing Resistance : Exhalation					Result
	Condition	No. of Sample	The dummy head position	Flow Rate 160 L/min	Exhalation Resistance Requirements in accordance with EN 149:2001 + A1:2009	
7.16	(T.C.)	15	Facing directly	2,0	FFP1 ≤ 3	<b>Passed</b>
			Facing vertically upwards	2,1		
			Facing vertically downwards	1,9	FFP2 ≤ 3	
			Lying on the left side	2,0	FFP3 ≤ 3	
			Lying on the right side	2,1		
<b>Conditioning : (T.C.) Temperature Conditioning</b>						
Article 7.17.2	<b>Clugging :</b> This test is not applied to Particle Filtering Half Mask which is not reusable. <i>(For single shift use devices, the clugging test is optional test. For re-usable devices test is mandatory.)</i>					
Article 7.17.3	<b>Penetration of filter material:</b> This test is not applied to Particle Filtering Half Mask which is not reusable.					
Article 7.18	<b>Demountable Parts:</b> There are no demountable parts on the product.					
Article 9	<b>Marking – Packaging:</b> Necessary markings are available on the product and its packaging.					
Article 10	<b>Information to be supplied by the manufacturer:</b> In each of the smallest commercially available packaging of the product, implementation (installation instruction) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined.					

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