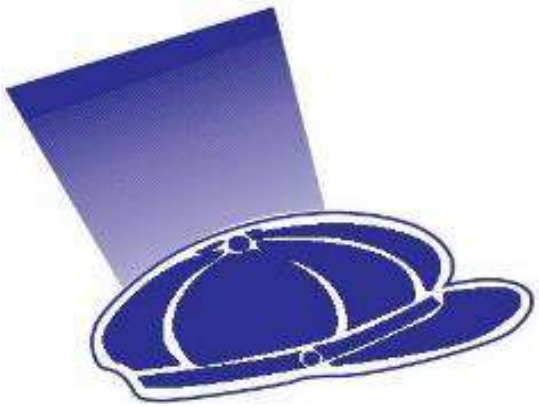


A&Z A&ZMED
Personal Protective Equipment

CE
TECHNICAL FILE

RESPIRATORY PROTECTIVE DEVICES - FILTERING HALF MASKS
TO PROTECT AGAINST PARTICLES

1.SCOPE

The technical file covers the quality and factory manufacturing control requirements used during the manufacture of Respiratory Protective Devices - Filtering Half Masks for Protection Against Particles, compliance with the essential health and safety requirements associated with the European Union Directive 2016/425/EU Provisions.

"İbişler Tekstil San. Ve Dış Tic. A.Ş. " Technical File;

EN 149: 2001 + A1: 2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

It has been prepared for the evaluation of the conformity of the standard.

Referenced standart sor documents;

EN, ISO, IEC vb. NO	NAME
EN 132	Respiratory protective devices - Definitions of terms and pictograms
EN 134	Respiratory protective devices - Nomenclature of components
EN 143	Respiratory protective devices-Particle filters-requirements, testing marking
EN 13274-7	Respiratory protective devices - Methods of test - Part 7: Determination of particle filter penetration
ISO 6941	Textile fabrics - Burning behaviour - Measurement of flame spread properties of vertically oriented specimens

2.MANUFACTURER'S INFORMATION

NAME	İbişler Tekstil San. Ve Dış Tic. A.Ş.
ADRESS	Orhangazi Mah. Tunç Cad. No:5 34358 Esenyurt / İSTANBUL
PRODUCTION PLACE	Orhangazi Mah. Tunç Cad. No:5 34358 Esenyurt / İSTANBUL
PHONE	0 212 602 04 05
FAX	0 212 602 04 07
E-MAIL	info@ibisler.com
PRODUCTION CONTROL REPRESENTATIVE	Naci ŞEN
QUALITY MANAGEMENT REPRESENTATIVE	Naci ŞEN
GENERAL MANAGER	Beytullah İBİŞ

3.PRODUCT INFORMATION

PRODUCT NAME	RESPIRATORY PROTECTION DEVICES - FILTERED HALF MASKS FOR PROTECTION AGAINST PARTICLES
TYPE	FFP2 V NR
CLASS	CATEGORY 3
BRAND	AZMED
PRODUCT MODEL	OLI-2025
YEAR OF PRODUCTION	2020
SIZE	-
COLOUR	White
FABRIC FEATURE	See Article 4

Our products comply with EN 149:2001+A1:2009 standards for protection from external factors related to breathing.

4.BILL OF MATERIALS AND SUPPLIERS

NR.	MATERIAL USED	FEATURE	MANUFACTURER INFORMATION
1	Spunbond	50 g/m2 SPUNBOND 30 g/m2 SPUNBOND	Kurt Kumaş San. Ve Tic. A.Ş.
2	Meltblown	25 g/m2 MELTBLOWN	Kurt Kumaş San. Ve Tic. A.Ş.
3	Lastik		Nokta Aksesuar
4	Tel		Nokta Aksesuar
5	Kutu		Karaca Serigrafi Matbaa Reklam Bilişim San. Ve Tic. Ltd. Şti.

5.PRODUCT PHOTO AND MARKING

6.INSTRUCTIONS FOR USE

FITTING INSTRUCTIONS:

1. Shape the mask into a dome shape with the nose clip on top and take it in your palm.

2. Mask; It is worn by holding the tires so that the strip on the upper side is on the bridge of the nose.

3. The rubber is placed on the auricle.

4. Adjust the nose clip by using both hands, tightening it according to your nose shape. Adjusting by compression with one hand can reduce the effect of the mask.

5. To understand the fit and tightness of the mask, take a deep breath and check that no air is entering around the nose. For this, readjust the nose clip if necessary. Then enter the area of work you work in.

IMPORTANT!

It is very important that users are trained in the correct use of the product. If there is difficulty in breathing or the mask is damaged or deformed, or if the face is not suitable, the mask should be changed immediately. Carefully following the instructions is an important step in safe mask use.

PRE-USE CHECKS:

1. Please read the instruction carefully before using.

2. Check the expiry date of the product.

3. Check the fit of the mask to the area used by looking at the markings on the mask.

4. Check the mask headbands.

5. Check the mask nose clip.

6. Check if the mask is damaged.

CONFORMITY CHECK:

With both hands, grasp the product from the front so as not to affect the fit of the mask on the face.

a) VALVE-FREE Masks, Breathe Strongly

b) VALVE Masks, Breathe Strongly

If there is leakage around the nose, readjust the nose clips to eliminate the leak.

Then repeat the above steps. If there is leakage from the mask edges, make sure the head straps are fitted correctly to eliminate the leak. Then repeat the above process.

If the necessary compliance cannot be achieved despite all procedures, do not enter the danger zone. Consult your supervisors.

STORAGE

• It should be kept in its original packaging.

• The temperature of the storage area should be between 20 ° C / + 40 ° C.

• Ambient Humidity should not be more than 80%.

• Half masks should be protected against the effects of aggressive chemicals, moisture and dirt.

• Half masks are disposable and maintenance free.

• If the above conditions are met, the shelf life is 3 years.

SECURITY PRECAUTIONS

• Failure to follow instructions and restrictions on the use of this product may reduce the effectiveness of the mask and cause illness or death.

• A properly selected mask should be used for your respiratory safety. Before using your product, it is recommended to consult a Workplace Physician or Occupational Safety Specialist about the suitability of the product for your intended use.

• Your product does not provide oxygen. Use only in environments with sufficient oxygen. Do not use this product when the oxygen concentration is less than 19.5%.

• Do not use this product in places containing hazardous contents.

• Do not use this product in explosive atmospheres.

• a) if breathing becomes difficult (b) if dizziness or other discomfort occurs, leave the work area immediately and go to fresh air.

• It is important that the mask fits your face well for full performance. Beard can prevent this. Wear the mask without a beard.

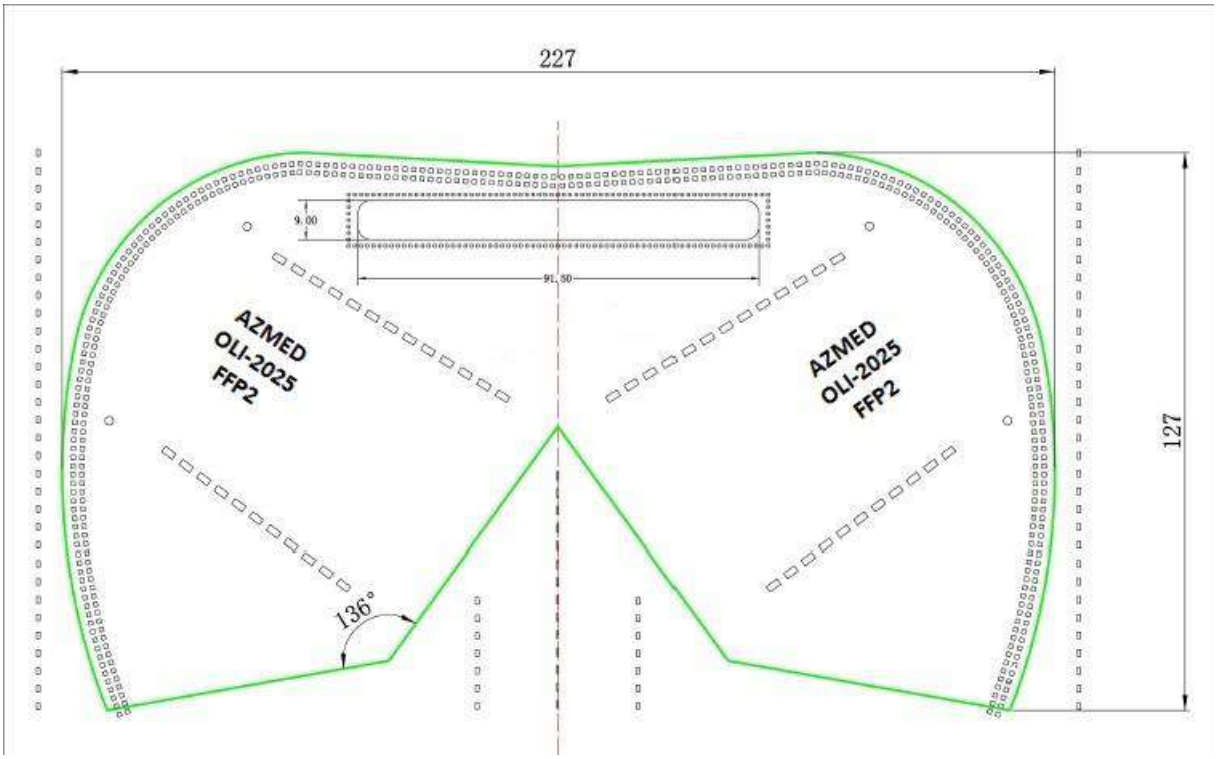
• Never alter or modify the mask.

• The NR marked masks are for single use only. It does not require maintenance. Please do not reuse the mask after a single use.

• Keep the masks away from direct sunlight until the moment of use.

7.PRODUCT PACKAGING

8.PRODUCT DRAWING AND VISUAL DIMENSIONS



9. EQUIPMENT LIST USED IN THE PRODUCTION PROCESS

NO	EQUIPMENT	PRODUCER
1	Automatic Folding Mask Making Machine	

10.RAW MATERIAL COMPONENT DEFINITIONS

KURT NONWOVEN SAN. VE TİC. A.Ş.	TECHNICAL DATA SHEET				
		sıra no	:	3311	
PRODUCT : Spunbond Nonwoven	TYPE OF RAW MATERIAL	: %100 POLYPROPYLENE	DATE	:	28.04.2020
ORDER NO : 0	COLOUR	: K-100 WHITE	WEIGHT	:	50
CUSTOMER : 0	APPLICATION	: H.PHOBIC	WIDTH	:	0
		:	QUANTITY	:	0

MADE TEST	AVARAGE VALUE (+/- 10 %)	METHOD
TENSILE STRENGTH N / 5 cm (MD)	115,00	NWSP 110.1.R0 (15)
TENSILE STRENGTH N / 5 cm (CD)	96,60	NWSP 110.1.R0 (15)
ELONGATION % (MD)	78,50	NWSP 110.1.R0 (15)
ELONGATION % (CD)	94,50	NWSP 110.1.R0 (15)
WEIGHT (gr / m²)	50	NWSP 130.1.R0 (15)
STRIKE THROUGH TIME (s)	0,00	NWSP 070.7 R0 (15)
REWET (g)	0,00	NWSP 070.9.R1 (15)

7

PREPARED BY
QUALITY CONTROL OPERATOR

M.ALİ KILIÇ

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QUALITY CONTROL MANAGER

İdil GÜNER

TECHNICAL DATA SHEET

		sıra no	:	3238	
PRODUCT : Spunbond Nonwoven	TYPE OF RAW MATERIAL	: %100 POLYPROPYLENE	DATE		24.03.2020
ORDER NO : 0	COLOUR	: K-100 WHITE	WEIGHT	:	30
CUSTOMER : 0	APPLICATION	: H.PHOBIC	WIDTH	:	0
		:	QUANTITY	:	0

MADE TEST	AVARAGE VALUE (+/- 10 %)	METHOD
TENSILE STRENGTH N / 5 cm (MD)	66,30	NWSP 110.1.R0 (15)
TENSILE STRENGTH N / 5 cm (CD)	41,20	NWSP 110.1.R0 (15)
ELONGATION % (MD)	81,20	NWSP 110.1.R0 (15)
ELONGATION % (CD)	88,50	NWSP 110.1.R0 (15)
WEIGHT (gr / m²)	30	NWSP 130.1.R0 (15)
STRIKE THROUGH TIME (s)	0,00	NWSP 070.7 R0 (15)
REWET (g)	0,00	NWSP 070.9.R1 (15)

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TECHNICAL DATA SHEET

ADRESS	: 2. OSB 83228 NOLU CADDE NO:16 BAŞPINAR/GAZİANTEP/TURKEY			DOCUMENT NO	: 3439
PRODUCT	: MELTBLOWN	TYPE OF RAW MATERIAL	: %100 POLYPROPYLENE	DATE	: 28.05.2020
ORDER NO	: 65623	COLOUR	: K-100 WHITE	WEIGHT	: 25
CUSTOMER	: DİNAMO	APPLICATION	: MELTBLOWN	WIDTH	: 17,5
				QUANTITY	: 216

MADE TEST	AVARAGE VALUE (+/- 10 %)	METHOD
TENSILE STRENGTH N / 5 cm (MD)	13,80	NWSP 110.1.R0 (15)
TENSILE STRENGTH N / 5 cm (CD)	12,40	NWSP 110.1.R0 (15)
ELONGATION % (MD)	42,00	NWSP 110.1.R0 (15)
ELONGATION % (CD)	53,60	NWSP 110.1.R0 (15)
WEIGHT (gr / m²)	25,0	NWSP 130.1.R0 (15)
HYDROSTATIC HEAD (mmH_2O)	412,00	NWSP 080.6.R0 (15)
BACTERIAL FILTRATION EFFICIENCY, BFE (%)	≥ 95	EN 14683:2019

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11.BASIC HEALTH AND SAFETY REQUIREMENTS

Basic Health and Safety Requiremenst (PPE Regulation EkII)			
Reference	**List of Basic Health and Safety Requirement**	**APPLICABLE (Yes/No)**	**Standart / Clause**
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 (7.6 / 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 / 7.6 / 7.7 / 7.10 / 7.11)
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.	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)

Basic Health and Safety Requiremenst (PPE Regulation EkII)			
Reference	**List of Basic Health and Safety Requirement**	**APPLICABLE (Yes/No)**	**Standart / Clause**
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***		
	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**		
	The manufacturer should give the user manual including the following issues together with the PPE that she puts on the market:	Yes	EN 149:2001+A1:2009 (10)
	a) Name and address of the manufacturer or its authorized representative,	Yes	EN 149:2001+A1:2009 (10)
	b)) 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)
	c) 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)
	ç) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;	Yes	EN 149:2001+A1:2009 (10)
	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)
	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)

Basic Health and Safety Requiremenst (PPE Regulation EkII)			
Reference	**List of Basic Health and Safety Requirement**	**APPLICABLE (Yes/No)**	**Standart / Clause**
	f) where applicable, the type of packaging suitable for transport;	Yes	EN 149:2001+A1:2009 (10)
	g) the significance of any markings (see point 2.12);	Yes	EN 149:2001+A1:2009 (10)
	ğ) References to the regulations, if any, specified in the last paragraph of Article 6 of this Regulation,	Yes	EN 149:2001+A1:2009 (10)
	h) The title, address and identification number of the notified body that designed the PPE.	Yes	EN 149:2001+A1:2009 (10)
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.	Yes	EN 149:2001+A1:2009 (7.13)
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)
	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.	Yes	EN 149:2001+A1:2009 (7.14)
	PPE models to be used by those who have to wear prescription glasses or contact lenses for normal vision should be compatible with prescription glasses or contact lenses.	Yes	EN 149:2001+A1:2009 (7.14)
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 (7.16 / 9 / 10)
	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 (7.16 / 9 / 10)

Basic Health and Safety Requiremenst (PPE Regulation EkII)			
Reference	**List of Basic Health and Safety Requirement**	**APPLICABLE (Yes/No)**	**Standart / Clause**
	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.	Yes	EN 149:2001+A1:2009 (7.16 / 9 / 10)
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.	Yes	EN 149:2001+A1:2009 (10)
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**		
	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	EN 149:2001+A1:2009 (10)
	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	EN 149:2001+A1:2009 (10)
	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.	Yes	EN 149:2001+A1:2009 (10)
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.	Yes	EN 149:2001+A1:2009 (7.13 / 7.18)
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**	

Basic Health and Safety Requiremenst (PPE Regulation EkII)			
Reference	**List of Basic Health and Safety Requirement**	**APPLICABLE (Yes/No)**	**Standart / Clause**
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.	**Hayır**	
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.	Evet	EN 149:2001+A1:2009 (Md. 9)
	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.	Evet	EN 149:2001+A1:2009 (Md. 9)
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.	**Hayır**	
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.	**Hayır**	
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***		
	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.	**Hayır**	
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.	**Hayır**	

Basic Health and Safety Requiremenst (PPE Regulation EkII)			
Reference	**List of Basic Health and Safety Requirement**	**APPLICABLE (Yes/No)**	**Standart / Clause**
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***		
	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**	
	The effective value of the vibration reflected on the user should never exceed the recommended limit value, taking into account the maximum daily exposure for the relevant part of the body.	**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**	
3.5	**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**	

Basic Health and Safety Requiremenst (PPE Regulation EkII)			
Reference	**List of Basic Health and Safety Requirement**	**APPLICABLE (Yes/No)**	**Standart / Clause**
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**	
	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 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.	**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**	
	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**	

Basic Health and Safety Requiremenst (PPE Regulation EkII)			
Reference	**List of Basic Health and Safety Requirement**	**APPLICABLE (Yes/No)**	**Standart / Clause**
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;	**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**	
	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**		
	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**	
	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**	

Basic Health and Safety Requiremenst (PPE Regulation EkII)			
Reference	**List of Basic Health and Safety Requirement**	**APPLICABLE (Yes/No)**	**Standart / Clause**
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***		
	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**	

Basic Health and Safety Requiremenst (PPE Regulation EkII)			
Reference	**List of Basic Health and Safety Requirement**	**APPLICABLE (Yes/No)**	**Standart / Clause**
	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 (7.6 / 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 7.17 / 9 / 10)
	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 (7.6 / 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 7.17 / 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 (7.6 / 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 7.17 / 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 (7.6 / 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 7.17 / 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 (7.6 / 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 7.17 / 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 (7.6 / 7.7 / 7.8 / 7.9 / 7.12 / 7.16 / 7.17 / 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**	

Basic Health and Safety Requiremenst (PPE Regulation EkII)			
Reference	**List of Basic Health and Safety Requirement**	**APPLICABLE (Yes/No)**	**Standart / Clause**
	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**		
3.11.1	**Solunum Cihazları**		
	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**	

12.MANUFACTURING AND QUALITY REQUIREMENTS

12.1 MANUFACTURING CONTROL

Technical File - Manufacturing Control Manual is the continuous internal control of manufacturing processes. This system includes the requirements for the controls performed to ensure compliance with the performance declared in the Declaration of Conformity, Medical Face Masks, the characteristics of which are described above.

Our company operates the Technical File - Production Control system in accordance with the requirements of these standards.

Our company has established the Manufacturing Control system, started certification studies and continues this system to ensure that the product supplied to the market is in compliance with the specified specifications. The Manufacturing Control system includes processes, regular audits, experiments and/or evaluations and use of results for the control of the manufacturing processes of the raw and other input materials or components, equipment, and the product.

12.2 QUALITY PLAN

Our company has determined and maintains its policy and procedures for Manufacturing Control in its quality plan. Quality plan involves the identification and specification of special processes that directly affect product quality and conformity. Quality plan includes the following features.

-Organizational structure of the manufacturer in terms of compliance and quality

-Document control

-Checking the component materials and the products it supplies

-Process control

-Conditions for the transportation and storage of the product,

-Requirements for inspection and testing of processes and products

-Methods to be applied in case of non-compliance

12.3 ORGANIZATION

12.3.1 Responsibility and Authority

The responsibility, authority and relationship of all staff which manage, perform and approve the works affecting compliance and quality are defined in the quality plan. While making the definition, the staff that is authorized in the following subjects is specified.

- Starting a process to prevent the production of nonconforming product,

- Identification and recording of any quality problem in the product

12.3.2 Management Representative

Our company has determined an authorized representative with appropriate knowledge and experience to ensure the implementation and maintenance of the Manufacturing Control audit and Quality Plan requirements. This representative may carry out audit and surveillance work alone.

REFERENCE

Management Representative Appointment Letter

12.3.3 Internal audits

Our company conducts internal audits to verify that the works comply with the planned regulations and to determine the effectiveness of the Manufacturing Control. Audits are scheduled according to the importance and status of the work performed. Audits and subsequent activities are carried out according to written documents. The results of the audits are reported and presented to the attention of the staff responsible for the audit. Staff responsible for this field, keep a record of the actions taken with timely measures when there is nonconformity in the audits.

REFERENCE

PR-01 Internal Inspectıon Procedure

PR-02 Nonconforming Product Control Procedure

PR-03 Improvement Corrective Action Procedure

FR-05 Corrective Action Form

FR-06 Internal Audit Tracking Report

FR-07 Internal Audit Report

FR-08 Internal Audit Plan

12.3.4 Management Review

The Production Control system is reviewed by the management once a year and relevant records are kept to ensure compliance and effectiveness.

REFERENCE

FR-01 Management Review Meeting Minutes

PR-03 Improvement Corrective Action Procedure

FR-05 Corrective Action Form

12.3.5 Subcontractor Services

Our company does not supply any subcontracting services other than its own resources. In such a case, this method will be a part of the quality control processes of our company by establishing a control method.

12.4 Document Control

Our company has determined and continues the written procedures to be applied to control all documents and data related to the requirements specified in these standards.

REFERENCE

PR-04 Documentation Control Procedure

PR-05 Quality Record Control Procedure

FR-02 Document Revision Request Form

FR-03 Distribution and Retrieval Form

12.5 CONTROL METHODS

12.5.1 Component Materials

Sufficient component materials are available to ensure that manufacturing and distribution are carried out at planned speeds, without adversely affecting the conformity of the product.

In order to ensure suitability of Medical Face Masks, specifications and tolerances have been created for the required component materials used in production and these are notified to the supplier in writing.

These control procedures confirm that input material suppliers can provide the required quality in the materials and are appropriate.

Production approval is not given without checking whether the materials supplied from different suppliers can affect the quality and conformity of the product.

REFERENCE

FR-13 Verification Form of Product Purchased

12.5.2 Product supplied by the customer

No component material in Medical Face Masks supplied by the customer is used and in such a situation, the necessary conditions will be provided by our company.

12.5.3 Control of Operations

The quality plan includes the following issues.

a) Conformity of all the inputs used with those used in the prototype of type approval

b) Conformity of the cutting process (combining the same parts from the same lot)

c) Stitch control, stitch pitch frequency control, stitch type control

d) Dimension control

e) Final product check (seams, sewing thread cleaning)

f) Label user manual and packaging control

REFERENCE

FR-14 Product Quality Control Form

FR-15 Plan for Monitoring and Measuring the Product

12.5.4 Transport, Storage and Distribution

It covers the procedures to ensure hygiene rules during transportation and storage of Medical Face Masks.

REFERENCE

PR-06 Transport, Storage, Maintenance and Shipment instruction

FR-04 Warehouse Tracking Form

12.6 INSPECTION AND TESTS

12.6.1 General

All necessary tools, equipment and staff are available to carry out the necessary inspections and tests.

All inspections made by the quality control staff are recorded, and if nonconforming products can be applied by separating, approval is given for the delivery of the products for which the nonconformity is corrected.

12.6.2 Input Component Material

Input component materials are examined and tested using the processes detailed in the input quality plans. If the quality plan of the supplier is also included in the quality plan of our company, the results of the tests carried out by the supplier can be used.

In order to prevent any deterioration in storage, necessary inspections of the materials continue.

12.7. NONCONFORMITY STATUS

12.7.1 General

Our company has documented and ensures its maintenance to prevent the use and application of the product that does not comply with the specified requirements, provided that it is reasonably applicable.

This control is necessary for identification, evaluation and decomposition (where practical) and disposal of the nonconforming product. All the procedures to be performed have been documented and a system has been formed to inform the user if the shipment of the nonconforming product cannot be prevented.

Nonconformity may occur in the following stages;

a) In the component materials in the warehouse,

b) If the product is processed,

c) In the transportation, storage and distribution of the product.

In these cases, when nonconforming material, product or process are determined, investigations are started to determine the causes of nonconformity and effective corrective measures are applied in accordance with the methods specified in the quality plan to prevent reformation of nonconformity.

REFERENCE

PR-02 Nonconforming Product Control Procedure

FR-09 Nonconforming Product Tracking Form

FR-13 Nonconforming Product Report

12.7.2 Nonconformity of component materials

In case the component materials are nonconforming, corrective measures may be as follows;

a) Reprocessing of component materials

b) Adjusting the manufacturing control to separate nonconforming components

c) Rejection and elimination of nonconforming material

REFERENCE

PR-02 Nonconforming Product Control Procedure

FR-09 Nonconforming Product Tracking Form

FR-13 Nonconforming Product Report

12.7.3 Nonconforming status of the final, finished product (from the result of the examination of the processes carried out)

Nonconforming Medical Face Masks are evaluated and necessary methods are followed to take corrective measures. Some measures consist of the following:

a) Reprocessing and acceptance of shipment of nonconforming product, if applicable,

b) If it is not feasible to be reprocessed, to be directed to alternative use,

c) Rejection of the product,

REFERENCE

PR-02 Nonconforming Product Control Procedure

FR-09 Nonconforming Product Tracking Form

FR-13 Nonconforming Product Report

12.8. Records

Manufacturing control results are recorded. Along with the details of the component materials subjected to the inspection, the location, date and time of the sample and other relevant information are recorded.

In case the component material or Medical Face Masks that are being studied do not meet the specification requirements, the corrective measures taken to ensure the product quality of the materials are recorded.

Records are archived and stored in a repeatable manner, for a minimum period of 5 years or longer which may be required by legislation in the country.

REFERENCE

PR-05 Quality Record Control Procedure

12.9. Training

Our company has established and applied methods for the training of all staff involved in the works affecting quality. Personnel who undertake special tasks have appropriate quality and expertise based on appropriate teaching, training or experience. Training records are kept.

Note- Although there may be a need for a proven training for the application of the quality mark, the marking pertains to the compliance of the product with the performance characteristics of the product using only written procedures. For this reason, although the use of “expert” staff may be required in marking as required by the legislation, a training condition that does not require special proof is required for expertise.

REFERENCE

PR-03 Improvement Corrective Action Procedure

FR-10 Training Registration Form, FR-11 Training Plan

1. OBJECTIVE

This procedure includes planning, programming, implementation, documenting the results and reporting to the management; Whether the QMS is effectively implemented in accordance with the quality policy and the quality manual, documented procedures and processes reflect current practices, responsibilities and services, staff, processes, services comply with the documented conditions, and Corrective and Preventive actions, processes and QMS ' is to show that it is executed systematically to improve its performance.

2. RESPONSIBILITIES AND IMPLEMANTATION

2.1. Planning Internal Audits

2.1.1. An Annual Internal Audit Plan is prepared by the Management Representative for the audits planned to be performed at least once a year and comes into effect after the approval of the Company Manager.

2.1.2. The auditors who will perform the internal audits are selected from the personnel who have been trained and certified in the internal audits.

2.1.3. Auditors should be independent of the department to be audited.

2.1.4. Its operation is like the QMS Internal Audit written below.

2.2. Preparation for Audit

2.2.1. According to the Annual Internal Audit Plan, the audits that are due are notified to the relevant units one week before the date of the audit by the Annual Representative Plan and the approval of the department manager to be audited is received.

2.3. Application of the Audit

2.3.1. Additional questions that are not included in the Internal Audit Question List can be asked, and the question asked is recorded in the Internal Audit Question List.

2.3.2. Corrective and Preventive Action Form is prepared by the auditors for each noncompliance found.

2.3.3. Corrective action is planned for the noncompliance found by the auditors, together with the relevant unit manager, and the completion date is determined and written on the Corrective and Preventive Action Form.

2.4. Reporting of the Audit

2.4.1. At the end of the audit, the Internal Audit Evaluation Report, which contains information about the audit, the result of the audit and the incompatibilities found, is created by the auditors.

2.4.2. After the audit, the auditors give the original of the Internal Audit Evaluation Report to the Management Representative and a copy to the relevant unit manager.

2.5. Tracking of Corrective Actions

2.5.1. Corrective actions related to nonconformities found as a result of the audit are recorded by the Management Representative on the Corrective and Preventive Actions Form.

2.5.2. Follow-up audit is carried out by the auditors under the coordination of the Management Representative on the completion date determined for the corrective actions. For this purpose, it gives the Internal Audit Evaluation Report of the unit to be monitored to the auditors.