Medical Mask - Type IIR

Product Code : MM 0299

Documents :

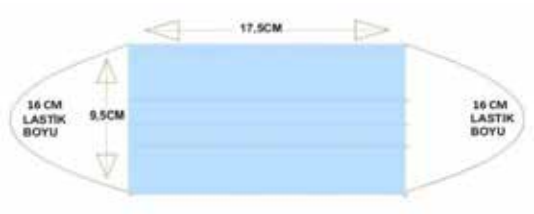
- TECHNICAL SHEET
- ATTESTATION OF CONFORMİTY
- EU DECLARATION OF CONFORMITY
- FDA CERTIFICATE
- LAB REPORT
- TECHNICAL EVALUATION REPORT
- TECHNICAL FILE

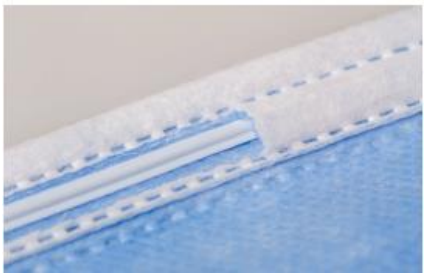
Standards :

- EN 14683 : 2019 + AC : 2019

Preparation date: 14.06.2020

T.017.01	TECHNICAL SHEET
BRAND	BIOBLOCKED
PRODUCT NAME	Medical Mask - Type IIR (NON-STERILE)
PRODUCT CODE	MM 0299





PRODUCT INFORMATION	
Model Description	3-layer 3-pleated medical mask.
Fabric	Outer Layer : Blue color 30 gr Spunbound.
	Middle Layer : 25 gr Meltblown.
	Inner Layer : White color 20 gr Spunbound.
Material	Nose wire.
	Mask rubber.

SEWING INSTRUCTIONS, LABEL AND IMPORTANT DETAILS	
General Production Instructions	All stitches will be ultrasonic.
	Mask size = Length: 17.5 cm, Width: 9.5 cm.
	Nose wire length 10 cm. Tolerance +/- 3 mm.
	The nose wire will be in the middle.
	Rubbers should not come out.
	Rubber length will be 16 cm. Tolerance +/- 10 mm.
	Rubber will be equal on the left and right sides.
	Rubbers should not shear off.
	The mask should be free of stains, dust and dirt.
	During start of work, when fabric or rubber is attached to the machine and when the machine is set, the products are checked randomly every hour.
CAUTION !!!	

PACKAGING DETAILS	
Packaging	We will work in accordance with the folding sample, if the folding sample has not reached you, request it.
Bag	The product code numbers on the bag and box used in the product must be the same as indicated on the swatch card.
	Ensure that the number of pieces in the bag or box are correct.
	Ensure the bag is closed properly and that there are no tears or holes.
Package	The pieces inside the package should be the same as the ones specified in the swatch card.
	The packages should not be broken, collapsed or torn.

UNIVERSAL CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD-168

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonisation of laws, regulations and administrative documentation of Member States on Medical Devices and European Economic Commission directive 93/68/EEC amending Medical Devices Directive dated 22 July 1993,

the products manufactured by

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ

at the following address

Selimpaşa Mahallesi 5001 Sokak No:6-A Silivri ISTANBUL / TURKEY

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name : BIOBLOCKED
Model : MM 0299
Type IIR
are tested according to the following initial type tests by the manufacturer

Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods

For the assessment of conformity, the following documents were also applied to:
Results of laboratory tests Çevre Endüstriyel Testing Laboratory Bacterial Filtration Efficiency, Microbial Cleanliness, Differential Pressure and Splash Resistance Pressure tests.

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the medical face masks manufactured and designed for use during the medical operations or similar medical situations with same requirements which require restriction of infectious materials to be spread to patients. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; reference to EN 14683 standard, type of mask (as indicated in Table 1) and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 30/06/2020 and valid until 29/06/2021 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

ISTANBUL –30/06/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Genel Müdür

Verify the validity with the QR Code

UNIVERSALCERT.COM

EU DECLARATION OF CONFORMITY

MANUFACTURER

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ
Selimpaşa Mahallesi 5001 Sokak No:6-A Silivri ISTANBUL / TURKEY

PRODUCT DESCRIPTION

Layered and molded medical device classified in the Class I - Medical Device to be used as protection against inhalation of viruses, bacteria, other microorganisms, allergens from the environment

Branda Name: BIOBLOCKED **Model**: MM 0299
Type IIR

The Producer / the Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely in accordance with the Producer's / the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- Government Regulation no. 93/42/EEC Medical devices establishing technical requirements for medical devices, in effective wording
- Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods
- Other relevant harmonized legislation
- Other relevant local, national and community standards
- For the assessment of conformity, the following documents were also applied to:
- Tests for irritation and delayed-type hypersensitivity
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Bavterial filtration efficiency
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Microbial Cleanliness
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Differential Pressure
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Splash Resistance Pressure

MARKING, LABELLING

Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied:
type of mask (as indicated in Table 1). EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered

MEASURES TO ENSURE CONFORMITY

The Producer / the Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

CE

Eren YELKENCİ
General Manager
30/06/2020

YELKENCİ HAZIR GİYİM
SANAYİ VE TİCARET A.Ş.

2020

CERTIFICATE OF REGISTRATION

This certifies that:

YELKENCI HAZIR GIYIM SANAYI VE TICARET A.S.
E5 Karayolu Uzeri. 5001 Sk No.6 Selimpasa
Silivri Istanbul, TR 34570

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	**3016879381**
DUNS No.:	**35-497-3328**
Device Classification Name:	**FACE MASK (EXCEPT N95 RESPIRATOR) FOR GENERAL PUBLIC/HEALTHCARE PERSONNEL PER IIE GUIDANCE**
Product Code:	**QKR**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: June 22, 2020

ANALYSIS REPORT

Report No. : **2012871E** Report Date : 22/06/2020

Applicant : YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

Address : Selimpaşa Merkez Mah. 5001.Sk No:6 34570 Silivri İstanbul/Turkey

Sample : Disposable 3 Layer Face Mask BioBlocked

Sample Package : Carton box

Sample Amount : 100 pieces

Sampling Point : -

Sampling Date : -

Sample Lot No. : 052023

Sample Carrying Conditions / Preservation Technique : -

Production Date : -

Packing Date : -

Expire Date : -

Producer Company : Yelkenci Hazır Giyim San. Tic. A.Ş.

Sample Receiving Time : 15/06/2020 12:00:00

Analysis Beginning Time : 15/06/2020 12:15:00

Analysis Completion Time : 22/06/2020

Following analysis results were obtained from the specimen which was delivered to Çevre Laboratory by hand to hand

Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method	Information
Differential Pressure								
DP - 1	Pa/cm²	27,2	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 126, 144
DP - 2	Pa/cm²	22,59	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 126, 144
DP - 3	Pa/cm²	26,98	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 126, 144
DP - 4	Pa/cm²	22,42	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 126, 144
DP - 5	Pa/cm²	23,04	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 126, 144
Bacterial Filtration Efficiency								
BFE - 1	%	99,4	≥95	≥98	≥98	97	EN 14683 - Annex B	122, 124, 129
BFE - 2	%	99,7	≥95	≥98	≥98	97	EN 14683 - Annex B	122, 124, 129
BFE - 3	%	99,6	≥95	≥98	≥98	97	EN 14683 - Annex B	122, 124, 129

Merve BİRAH
Assistant Laboratory Responsible of Microbiology Laboratory

Approved by
22/06/2020
Ömer Yasin BALIK
Laboratory Manager

Çevre Endüstriyel Analiz Laboratuvarı Hiz. Tic. A.Ş. Merkez Mahallesi Tatlıpınar Sokak No:13 Mart Plaza Kat:2/A Kağıthane / İstanbul

ANALYSIS REPORT

Report No. : **2012871E** Report Date : 22/06/2020

Following analysis results were obtained from the specimen which was delivered to Çevre Laboratory by hand to hand

Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method	Information
BFE - 4	%	99,2	≥95	≥98	≥98	97	EN 14683 - Annex B	122, 124, 129
BFE - 5	%	99,8	≥95	≥98	≥98	97	EN 14683 - Annex B	122, 124, 129
Mean Positive Control Count	cfu	1972	-	-	-	-	EN 14683 - Annex B	
Negative Control Count	cfu	<1	-	-	-	-	EN 14683 - Annex B	
Mean Particle Size (MPS)	µm	3,2	-	-	-	-	EN 14683 - Annex B	
Microbial Limit - Bioburden								
Bioburden - 1	cfu/g	20	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 2	cfu/g	11	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 3	cfu/g	19	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 4	cfu/g	15	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 5	cfu/g	14	≤30	≤30	≤30	97	ISO 11737-1	120, 131

Source of Limit Ranges : 97 Medikal Yüz Maskelerinin Test Metodları ve Performans Gereksinimleri (EN 14683)

A: Acceptable NA: Not Acceptable

MU: Measurement Uncertainty

Method
EN : European Standard
ISO : International Organization for Standardization

Information
120 : Bioburden : Aerobic Bacteria and Mold-Yeast
Pozitive Controls : Bacillus atrophaeus
Extract Fluid : Peptone, Tween with Sodium Chloride
Extract Fluid Volume : 300 mL
Plating Method : Membrane Filtration
Agar Medium : Tryptic Soy Agar for Aerobic Bacteria Count and Sabouraud Dextrose Agar with Chloramphenicol for Mold and Yeast Count
Recovery Efficiency : Repetitive Rinse Method
Aerobic Bacteria : Plates are incubatede 3 days at 30-35°C, then enumerated.
Yeast - Mould : Plates are incubatede 5-7 days at 20-25°C, then enumerated.

122 : Conditioning Parameters : 85± 5 relative humidity and 21± 5 °C de minimum 4 hours

123 : Flow rate during testing : 8 L/dk

124 : Flow rate during testing : 28.3 L/dk
Test performed with the inside of the medical face mask in contact with the bacterial challenge.

126 : The mask analyzed according to the results of Differential Pressure provides EN 14683 Table 1. Type I, Type II and Type IIR limits.

129 : The mask analyzed according to the results of Bacterial Filtration Efficiency (BFE) provides EN 14683 Table 1. Type I,Type II and Type IIR limits.

131 : The mask analyzed according to the results of Microbial Limit - Bioburden provides EN 14683 Table 1. Type I, Type II and Type IIR limits.

144 : The test was applied from the inner surface on the mask to the outher surface, as required by the standard.

Merve BİRAH
Assistant Laboratory Responsible of Microbiology Laboratory

Approved by
22/06/2020
Ömer Yasin BALIK
Laboratory Manager

Çevre Endüstriyel Analiz Laboratuvarı Hiz. Tic. A.Ş. Merkez Mahallesi Tatlıpınar Sokak No:13 Mart Plaza Kat:2/A Kağıthane / İstanbul

ANALYSIS REPORT

Report No. : **2012871E** Report Date : 22/06/2020

Note

1. When request, the conformit assessment is carried out in accordance with the legal regulations and standards or the decision rules which are agreed with the customer.
2. Descriptive information about the samples / sampling in the analysis report has been declared by the customer. Our laboratory is not responsible for the legal losses.
3. Analysis report covers samples/sampling that comes to the laboratory.
4. This report and results don't not be copied and printed partially or completely without permission of Cevre Industrial Analysis Laboratory for any commercial and advertising purposes.
5. This report shall not be used official purposes related to Enviromental Regulations.
6. The test report without sign is not valid.

End of Report

Merve B□RAH
Assistant Laboratory Responsible of Microbiology Laboratory

Approved by
22/06/2020
Ömer Yasin BALIK
Laboratory Manager

Çevre Endüstriyel Analiz Laboratuvarı Hiz. Tic. A.Ş. Merkez Mahallesi Tatlıpınar Sokak No:13 Mart Plaza Kat:2/A Kağıthane / □stanbul

ANALYSIS REPORT

Report No. : **2013579E** Report Date : 29/06/2020

Applicant : YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Address : Selimpaşa Merkez Mah. 5001.Sk No:6 34570 Silivri İstanbul/Turkey

Sample : Disposable 3 Layer Face Mask BioBlocked

Sample Package : Carton box
Sample Amount : 100 pieces
Sampling Point : -

Sampling Date : -
Sample Lot No. : 052023

Sample Carrying Conditions / Preservation Technique : -

Production Date : -
Packing Date : -
Expire Date : -
Producer Company : Yelkenci Hazır Giyim San. Tic. A.Ş.
Sample Receiving Time : 15/06/2020 12:00:00
Analysis Beginning Time : 23/06/2020 12:15:00
Analysis Completion Time : 29/06/2020

Following analysis results were obtained from the specimen which was delivered to Çevre Laboratory by hand to hand

Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method	Information
Splash Resistance Pressure								
Splash Resistance Pressure	kPa	≥16	-	-	≥16	97	ASTM F1862	122, 141, 142, 147
Number of Masks Analyzed	-	29	-	-	-	-	-	
Number of Passed Masks Analyzed	-	29	-	-	-	-	-	
Analyzed Mask Surface	-	Outside	-	-	-	-	-	
Point of Analysis	-	Midpoint	-	-	-	-	-	

Source of Limit Ranges : 97 Medikal Yüz Maskelerinin Test Metodları ve Performans Gereksinimleri (EN 14683)

A: Acceptable NA: Not Acceptable

MU: Measurement Uncertainty

Method ASTM: American Society for Testing and Materials

Information 122 : Conditioning Parameters : 85± 5 relative humidity and 21± 5 °C de minimum 4 hours

Okan PELİT
Laboratory Responsible

Approved by
29/06/2020
Ömer Yasin BALIK
Laboratory Manager

Çevre Endüstriyel Analiz Laboratuvarı Hiz. Tic. A.Ş. Merkez Mahallesi Tatlıpınar Sokak No:13 Mart Plaza Kat:2/A Kağıthane / İstanbul
Tel.: (0212) 321 09 00 (pbx) Faks: (0212) 321 09 75 e-mail: info@cevreanaliz.com www.cevreanaliz.com

ANALYSIS REPORT

Report No. **: 2013579E** Report Date **:** 29/06/2020

141 : 29 masks were analyzed. All of the analyzed masks gave "successful" results in tests performed at 16 kPa pressure.
142 : The mask analyzed according to the results of Splash Resistance Pressure provides EN 14683 Table 1. Type IIR limit.
147 : Test Parameters : 58,7% relative humidity and 22,4°C

Note

1. When request, the conformit assessment is carried out in accordance with the legal regulations and standards or the decision rules which are agreed with the customer.
2. Descriptive information about the samples / sampling in the analysis report has been declared by the customer. Our laboratory is not responsible for the legal losses.
3. Analysis report covers samples/sampling that comes to the laboratory.
4. This report and results don't not be copied and printed partially or completely without permission of Cevre Industrial Analysis Laboratory for any commercial and advertising purposes.
5. This report shall not be used official purposes related to Enviromental Regulations.
6. The test report without sign is not valid.

End of Report

Okan PEL
Laboratory Responsible

Approved by
29/06/2020
Ömer Yasin BALIK
Laboratory Manager

Çevre Endüstriyel Analiz Laboratuvarı Hiz. Tic. A.Ş. Merkez Mahallesi Tatlıpınar Sokak No:13 Mart Plaza Kat:2/A Kağıthane / İstanbul
Tel.: (0212) 321 09 00 (pbx) Faks: (0212) 321 09 75 e-mail: info@cevreanaliz.com www.cevreanaliz.com

UNIVERSAL
CERTIFICATION

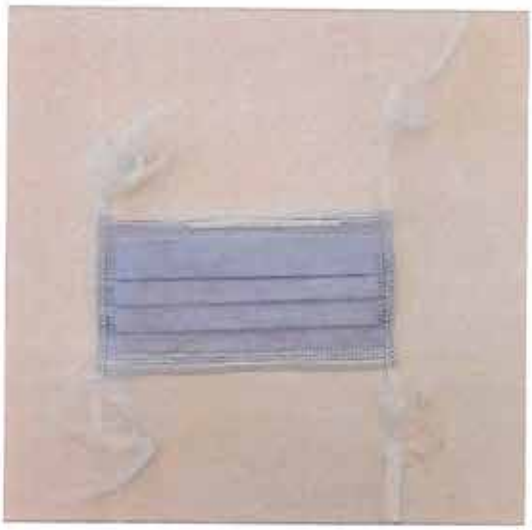
TECHNICAL EVALUATION REPORT

REPORT DATE / NO: 30.06.2020 / 05-2020-T0176

Manufacturer: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ
Address: Selimpaşa Mahallesi 5001 Sokak No:6-A Silivri ISTANBUL / TURKEY

The medical masks manufactured by the above manufacturer, are evaluated based on the Annex ZA of harmonised standard EN 14683/AC:2019 and the essential health and Safety requirements of 93/42/EEC, Medical Device Directive for Class I products on avoluntary base upon the manufacturer request.

Product Description: Medical Face Mask
Trademark: BIOBLOCKED **Model:** MM 0299



As a third party evaluation, the technical file provided by the manufacturer is evaluated and the samples provided by the manufacturer are tested according to Annex ZA of the EN 14683/AC:2019 standard.
See Annex I: Test report provided by Çevre Endüstriyel Analiz Laboratuarı 28.05.2020 **2011100E**, 29.06.2020 **2013312E** date and with report number.

This report or the issued certificate, in case the report is positive, does not take over orchange the sole reponsibility of the manufacturer covered under 93/42/EEC Medical Device Directive. The manufacturer shall fulfil all responsibilities for Class I products under 93/42/EEC Medical Device Directive.

The results of the evaluation are as follows;

A- Review of the technical file

The manufacturer owns a technical file based on the requirements of 93/42/EEC Medical Device Directive in which the essential health and Safety requirements for Class I products are handled and have documented procedures to fulfil these requirements. The positive result of this report or the possible certificate to be issued based on positive result of this report shall not be used as the share of the responsibility of manufacturer on the fulfilment of any responsibility to be fulfilled before putting the product on the EU market.

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

B- Product Test Results

The tests referenced in Annex ZA are conducted on the samples provided by the manufacturer and the results are evaluated;

1. Biocompatibility

In the evaluation of the technical file, it was observed that the manufacturer has established a mechanism for the evaluation of raw materials or semi-finished goods on their biocompatibility. The manufacturer claims that the request and evaluation of proofs for biocompatiblity of the goods is an essential part of the procurement policy and declares that the produced masks are complies with the biocompatibility requirements and have authorised responsible staff members for ensuring the success of this policy. It is considered that the manufacturer have an effective policy for the biocompatibility of the product.

2. Bacteria Filtration Efficiency

At least 5 samples are subjected to a bacteria aerosol with a flow rate of 28.3 L/min for 2 minutes with a test setup defined in the Annex B of EN 14683/AC:2019 standard. With the results of the incubation of samples taken in different particule sizes are shown in the annexed test report.

The minimum bacteria filtration efficiency performance required by each performance classes are shown below;

Test	Type I*	Type II	Type IIR
Bacterial Filtration Efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
* Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.			

According to the evaluation of the results of 5 samples tested, the minimum bacteria filtration efficiency is given as **99,1%**. According to this result, the bacteria filtration efficiency performance of the masks is classifified as **Type IIR**.

It was observed that the avarage positive control values and negative control value is also reported as a confidence parameter of the test result are meaningful.

3. Microbial Cleanliness (Bioburden)

It is expected to have the number of colony forming units per gram to be lower than 30 for all performance class of masks according to the test result based on ISO 11737-1 standard.

In the evaluation of the test result, the maximum count of the colony forming unit is reported as **28** For this test result the samples complies the requirement for all performance classes (Type I, Type II and Type IIR).

4. Differential Pressure

The test is conducted to measure the breathing resistance as the differantial pressure and the expected result for Type I and Type II classes is not to be higher than 40 Pa/cm^2 and for Type IIR class not to be higher than 60 Pa/cm^2.

According to the test results, the highest differantial pressure measured is **52,86** Pa/cm^2 and the samples complies the requirement for all performance classes (Type I, Type II and Type IIR).

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

5. **Splash Resistance Pressure**

In the test, done according to ISO 22609:2004 the product's splash resistance is expected to be equal or higher than 16kpa for the Type 2R class.

All 15 samples tested were able to provide Type IIR performances as 16kPa resistance.

C- Summary and Conclusion

Evaluation	Requirement	Result	Classification
Bacterial Filtration Efficiency (BFE), (%)	≥ 95 % – Type I ≥ 98 % – Type II ≥ 98 % – Type IIR	98,1 %	Type I Type II Type IIR
Differential pressure (Pa/cm2)	< 40 – Type I < 40 – Type II < 60 – Type IIR	52,86	Type I Type II Type IIR
Splash resistance pressure (kPa)	Not Required – Type I Not Required – Type II ≥ 16 – Type IIR	> 16	Type IIR
Microbial cleanliness (cfu/g)	≤ 30 – Type I ≤ 30 – Type II ≤ 30 – Type IIR	29	Type I Type II Type IIR
Overall Performance Classification			**Type IIR**

– End of Report –

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ.
Necip Fazıl Bulvarı, Keyap Sitesi, E2 Blok, No:44/84
Yukarı Dudullu-Ümraniye/İSTANBUL
Telefon: 0216 455 80 80 Faks: 0216 455 80 08
Sarıgazi V.D. 892 025 8722

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

TABLE OF CONTENTS - ABOUT THE MANUAL

Technical File - Manufacturing Control Manual has been prepared in accordance with EN 13795-1: 2019 Standard in order to introduce the production facility control system and explain the basic elements of the system. In addition to guiding the establishment of the system and preparation of the system documentation, the Control Manual is used to introduce the system to the customer and third parties. Manufacturing Control Manual is prepared by Production Control Representative, Quality Management Representative, and issued after checked and approved by the Company Manager.

On the pages of the Control Manual, "**YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ**" logo, "Technical File - Production Control Manual" phrase, Department Name, Document No (**TD-03**), Issue Date, Revision Date, Revision No, Page No and the information of the persons who Prepared (Title and Signature) Controlled (Title and Signature) and Approved (Title and Signature) are found. Page No; is given as "page no/total page no".

The revision made in the Technical File - Manufacturing Control Manual is applied to the entire document, the manual revision number is increased by 1, the revision date is updated, the revision reason is recorded in the revision reason section on each page and reissued.

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Management Representative GÜRSEL ÖZCANLI	Company Manager ÖZGÜR ÖZENİR

Other issues related to revision and distribution of the manual are applied according to the "PR.01 Document Control Procedure".

0. INTRODUCTION

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ

Technical File - Manufacturing Control Manual;

- EN 14683:2019+AC:2019 Medical Face Masks – Requirements and Test Methods

It has been prepared as part of the system used to evaluate the compliance with its standards.

The Technical File - Manufacturing Control Manual process is designed for the implementation of harmonized European standards for Medical Face Masks, regardless of whether the marking is applied by legislation or not.

1. SCOPE

Technical File - Manufacturing Control Manual covers the quality and factory manufacturing control requirements used during the manufacture of Medical Face Masks, and compliance with the Basic Health and Safety Requirements Associated with the European Union Directive 93/42/EEC.

Basic Requirements of Directive 93/42/EEC:

8.1. Medical devices and manufacturing procedures should be designed to eliminate or reduce the risk of infection to the patient, practitioner and third parties. The design should be easily implemented and minimize the contamination of the patient from the medical device or the medical device from the patient during use, if necessary.

- **Name of the Company:** *YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ*
- **Company Address:** E5 Karayolu Üzeri 5001. Sokak No:6 Selimpaşa Silivri İSTANBUL

2. REFERENCE STANDARD AND/OR DOCUMENTS

Reference is made in this manual to other standards and/or other documents, with or without specifying the date. These references are stated in appropriate places in the text and are listed below.

EN,ISO,IEC vb.NO	NAME
EN 14683:2019+AC:2019	Medical Face Masks - Requirements and Test Methods
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and experiment in a risk management process
EN ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Identification of the microorganism population on products
ISO 22609:2004	Clothing for protection against infectious agents-Medical face masks-Test method for resistance to penetration of synthetic blood (fixed volume, horizontally eclipsed)
EN ISO 15223-1	Medical devices - Symbols to be used in medical device labels, labeling and information to be presented - Part 1: General requirements
EN 1041 + A1	Information Provided by Medical Device Manufacturers
EN ISO 15223-1	Medical devices - to be used in Medical Device Labels, Labeling and Information to be Provided Symbols - Part 1: General Requirements
93/42/EEC	Medical Devices Directive (Annex 1, Art. 23)

3. Product Description

3.1 Product Description

PREPARED BY		APPROVED BY
Production Control Representative ŞABAN KARADENİZ	Quality Management Representative GÜRSEL ÖZCANLI	Company Manager ÖZGÜR ÖZENİR

Medical Face Masks we manufacture are Medical Face Masks that aim to limit the infectious agents from staff to patients during surgical procedures and in other medical environment with similar requirements and gowns with a suitable microbial barrier, they may also be effective in reducing the spread of infective agents by asymptomatic carrier or patient with clinical symptoms, our company produces Medical Face Masks with these features in a high quality and hygienic environment.

3.2 Product Model No : MM 0299 (Type IIR)
3.3 Product Dimension : 17,5 cm X 9,5 cm
3.4 Brand Name : BIOBLOCKED

3.5 Factory Manufacturing Control:
Documentation of the manufacturing control system is designed to ensure that the quality guarantee is widely understood, to ensure that the required product properties are provided, and to control the efficient operation of the manufacturing control system.

3.6 Risk Assessment of PPE for Protection

3.7 Materials and Intermediates Used

NO	MATERIAL USED	SPECIFICATION	PRODUCER INFORMATION
1	Spunbound Fabric	Exterior: 30gr /m² – İç : 20 gr/m²	Bayteks
2	Meltblown Filtration Fabric	Middle : 25 gr /m²	Bayteks
3	Rubber	Rubber	Slayt Örme
4	Nose Wire	Nose Wire	Şule Kablo

3.8 Product Photos (Annex A)
3.9 Marking (Annex B)
3.10 Meaning of Symbols in Product Packaging (Appendix C)

4. REQUIREMENTS
4.1 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.

4.2 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

4.3 ORGANIZATION

4.3.1 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

4.3.2 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

4.3.3 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

Internal Audit Procedure
Nonconforming Product Control Procedure
Corrective and Preventive Actions Procedure

4.3.4 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

MR Meeting Minutes

4.3.5 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.

4.4 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

Document Control Procedure

Record Control Procedure

5 CONTROL METHODS

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.

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.

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

5.4 Transport, Storage and Distribution

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

REFERENCE
Transport, Storage, Maintenance and Shipment instruction

6 INSPECTION AND TESTS

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.

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.

7 NONCONOFRMITY STATUS

7.1General

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
Nonconforming product control procedure

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
Nonconforming product control procedure

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
Nonconforming product control procedure
Quality plan

8 Records

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
Sample Label
Analysis Reports
Quality Records Control Procedure

9 Training

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

Training records
Training plan

Annex A

PRODUCT PHOTOS

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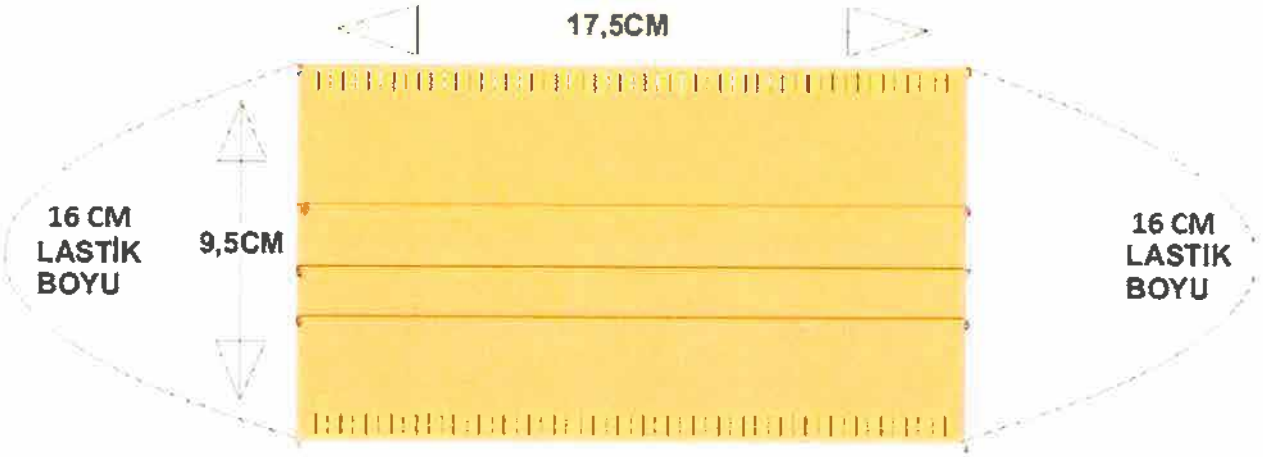


Annex B

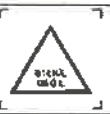
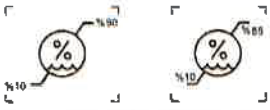
MARKING

COMPANY TITLE
Address Information

13.3. Information that should be on the label:
a) The manufacturer's name or commercial name and address must be included, for imported medical devices, the name or commercial name and address of the authorized representative and/or importer should also be included on the label or on the sales packaging or in the instruction manual,
b) Detailed information that defines the contents of the package and the medical device, and especially for the user,
c) "STERILE" phrase where necessary,
ç) Party code or serial number with the expression "LOT", where necessary,
d) Expiry date in months and years, where necessary,
e) The phrase "disposable", where necessary,
f) If the medical device is custom made, the words "custom made device",
g) If the medical device is intended for clinical investigations, the words "exclusively for clinical investigations",
ğ) Special storage and/or conditions of use,
h) Special storage and/or conditions of use,
ı) Any warnings and/or precautions to take,
i) Production date to be specified in the batch/lot or serial number for active medical devices, apart from subparagraph (d),
j) Where applicable, method of sterilisation,
k) Where applicable, method of sterilisation,
l) If the medical device contains a human blood derivative, the related phrase is sought.

Annex C

Meaning of Symbols in Product Packaging

SEMBOL	SEMBOLÜN BAŞLIĞI	SEMBOLÜN AÇIKLAMASI	ÖRNEK
	Manufacturer	Specifies the medical device manufacturer, as defined in the EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	 **Ad Address**
	Manufacture date	Indicates the date the medical device was manufactured.	 **2020 - 06**
	Expiration date	Shows the expiration date of the medical device.	 **2021 - 06**
	Non-sterile (Non Sterile)	Indicates that a medical device has not been subjected to sterilization.	
	Do not use if the packaging is damaged	Indicates that the medical device should not be used if its packaging is damaged or opened.	
	Keep it dry.	Indicates that the medical device should be protected from moisture.	
	Temperature limitation	Indicates the temperature limits to which the medical device can be safely exposed.	
	Moisture limitation	Indicates the range of humidity to which the medical device can be safely exposed.	
	Do not reuse	Indicates that the medical device is intended for single use or for use on a single patient during a single procedure.	**Disposable PPE, "Do not reuse!"**
	See instructions for use	Indicates that the user should consult the instructions for use.	

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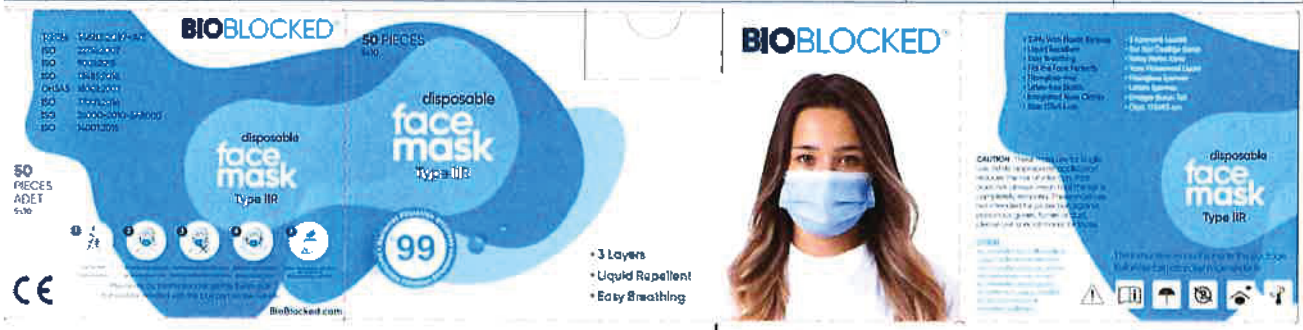

BIOBLOCKED

Disposable Face Mask

ENG	TR
• 3-Ply With Elastic Earloop	• 3 Katmanlı Lastikli
• Liquid Repellent	• Sıvı İtici Özelliğe Sahip
• Easy Breathing	• Kolay Nefes Alma
• Fits the Face Perfectly	• Yüze Mükemmel Uyum
• Fibreglass-free	• Fiberglass İçermez
• Latex-free Elastic	• Lateks İçermez
• Integrated Nose Clamp	• Entegre Burun Teli

ENG

Biobtocked mask, with its face-compatible 3D design; can be used without disturbing thanks to its soft and flexible structure. It allows air-pass that makes for easy breahing.
The mask is anti allergenic and has a 3 ply structure.
The mask is for single use only. Replace as necessary.

TR

BioBlocked maske, Yüze uyumlu 3 boyutlu tasarımı ile yumuşak ve esnek yapısı sayesinde rahatsız etmeden kullanılabilir.
Hava geçirir ve kolay nefes almaya imkan verir. Alerji Yapmaz.
3 katlı yapıya sahiptir. Tek kullanımlıktır. Gerektikçe değiştiriniz.

How to wear a mask

Store in cool,dry,dust-free conditions.
Serin,rutubetsiz ve tozsuz yerde saklayınız.

TS EN	14683:2019+AC	OHSAS	18001:2007
ISO	22716:2007	ISO	27001:2014
ISO	9001:2015	ISO	26000:2010-SAB000
ISO	13485:2016	ISO	14001:2015

Product: MM 0299

8 682753 531615

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Gültepeoya Merkez Mah. 5001 Sk. No. 6 Silivri - İstanbul - Türkiye

MASK INSTRUCTIONS FOR USE

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- Hands are washed with soap for at least 20 seconds.
- The mask is worn by holding the rubber with the folded part on the outside, the strip on the top side of the nose bridge.
- The rubber is placed on the ear.
- It is placed by gently pressing on the strip corresponding to the nose.
- The mask is placed to cover the nose, mouth and chin completely.
- Always replace your mask if it is moistened, torn or dirty during use.
- Take off your mask by holding the rubber.
- It is disposable.

Annex D

Essential Health and Safety Requirements

ESSENTIAL REQUIREMENTS

I. GENERAL REQUIREMENTS

1) Medical devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons.

Any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

In the design of the medical device;

- reducing, as far as possible, the risk of use error due to the ergonomic features of the medical device and the environment in which the device is intended to be used (design for patient safety), and
- consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for professional, disabled or other users) should be included

2) The solutions adopted by the manufacturer for the design and construction of the medical devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles:

- eliminate or reduce risks as far as possible (inherently safe design and construction),
- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted

3) Medical devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 3 (o) of this Regulation, as specified by the manufacturer.

4) The characteristics and performances referred to in sections 1, 2 and 3 of this Annex must not be adversely affected to such a degree that the clinical condition and safety of the patients and of other persons are compromised during the lifetime of the medical device as indicated by the manufacturer, when the medical device is subjected to the stresses which can occur during normal conditions of use.

5) Medical devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

6) Any undesirable side effects of the medical device must constitute an acceptable risk when weighed against the performances intended.

6.a) Demonstration of conformity of the medical device with the essential requirements must include a clinical evaluation in accordance with Annex X.

II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

7) Chemical, physical and biological properties:

7.1. Medical devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in "General requirements" of this Annex.

- the choice of materials used, particularly as regards toxicity and, where appropriate flammability,

- the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the medical device.
- where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.

7.2. Medical devices must be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and the duration and frequency of the exposure.

7.3. Medical devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures. If medical devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing those products and that their performance is maintained in accordance with the intended use.

7.4. Where a medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Human Medical Products Licensing Regulation and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the methods specified in the related Regulation.

For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the medical device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the medical device. In this scientific opinion, data prepared by the notified body regarding the manufacturing process and the benefit of adding this substance to the medical device are taken into account.

Where a medical device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the medical device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/ risk profile of the incorporation of the human blood derivative into the medical device. In this scientific opinion, data prepared by the notified body regarding the manufacturing process and the benefit of using this substance in the medical device are taken into account.

Where changes are made to an ancillary substance incorporated in a medical device, in particular related to its manufacturing process, the notified body shall be informed of the changes. Notified body re-apply to the Ministry or European Medical Products Assessment Agency (EMEA) with whom it has previously been consulted in order to confirm the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the medical device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.

When the competent authority has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.

7.5. The medical devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with the Regulation on Classification, Packaging and Labeling of Hazardous Substances and Preparations published in the Official Gazette dated 26/12/2008 and numbered 27092.

In parts of a medical device or a medical device itself intended to administer and/or remove medicines, body liquids or other substances to or from the body, or medical devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with the Regulation on Classification, Packaging and Labeling of Hazardous Substances and Preparations, these devices must be labeled on the medical device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a medical device containing phthalates.

If the intended use of such medical devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the

essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and if applicable, on appropriate precautionary measures.
7.6. Medical devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.
8) Infection and microbial contamination:
8.1. The medical devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use.
8.2. Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.
Notified Bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.
8.3. Sterile medical devices must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.
8.4. Sterile medical devices must have been manufactured and sterilised by an appropriate, validated method.
8.5. Medical devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions.
8.6. Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the medical devices are to be sterilised prior to use, minimise the risk of microbial contamination.
The packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer.
8.7. The packaging and/or label of the medical device must distinguish between identical or similar products sold in both sterile and non-sterile condition.
9) Construction and environmental properties:
9.1. If the medical device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performance of the devices.
Restrictions on use must be indicated on the label or in the instruction for use.
9.2. Medical devices must be designed and manufactured in such a way as to remove or minimise as far as possible:
- the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional, and where appropriate the ergonomic features,
- risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure, and acceleration,
- the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,
- risks arising where maintenance or calibration are not possible (as with implants), from ageing of the materials used or loss of accuracy of any measuring or control mechanism.
9.3. Medical devices must be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances which could cause combustion.
10) Medical devices with a measuring function:
10.1. Medical devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.
10.2. The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.
10.3. The measurements made by medical devices with a measuring function must be expressed in units of measurement specified in the Regulation on the International Units System published in the Official Gazette dated 21/6/2002 and numbered 24792.
11) Protection against radiation:
11.1. General:

11.1.1. Medical devices shall be designed and manufactured such that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.
11.2. Intended radiation:
11.2.1. Where medical devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such medical devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.
11.2.2. Where medical devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.
11.3. Unintended radiation:
11.3.1. Medical devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is be reduced as far as possible.
11.4. User Manuals:
11.4.1. The operating instructions for medical devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.
11.5. Ionising radiation:
11.5.1Medical devices intended to emit ionising radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.
11.5.2. Medical devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way, as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and use.
11.5.3. Medical devices emitting ionising radiation intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of the radiation.
12) Requirements for medical devices connected to or equipped with an energy source:
12.1. Medical devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to their intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.
12.1.a. For medical devices which incorporate software or which are medical Software in themselves, the software must be validated according to state of the art taking into account the principles of development lifecycle, risk management, validation and verification.
12.2. Medical devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.
12.3. Medical devices where the safety of the patient depends on an external power supply must include an alarm system to signal any power failure.
12.4. Medical devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.
12.5. Medical devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.
12.6. Protection against electrical risks:
Medical devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided that the devices are installed correctly.
12.7. Protection against mechanical and thermal risks:
12.7.1. Medical devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.
12.7.2. Medical devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

12.7.3. Medical devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.
12.7.4. The terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimise all possible risks.
12.7.5. Accessible parts of medical devices excluding any parts or areas intended to supply heat or reach given temperatures and their surroundings must not attain potentially dangerous temperatures under normal use.
12.8. Protection against the risks posed to the patient by energy supplies or substances:
12.8.1. Medical devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.
12.8.2. Medical devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.
Medical devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.
12.9. The function of the controls and indicators must be clearly specified on the medical devices. Where a medical device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.
13) Information supplied by the manufacturer:
13.1. Each medical device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instruction leaflet is needed for devices in Class I or Class IIa if they can be used completely safely without any such instructions.
13.2. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the medical device.
13.3. The label must bear the following particulars:
a) The manufacturer's name or commercial name and address must be included, for imported medical devices, the name or commercial name and address of the authorized representative and/or importer should also be included on the label or on the sales packaging or in the instruction manual,
b) Detailed information that defines the contents of the package and the medical device, and especially for the user,
c) "STERILE" phrase where necessary,
d) Lot code or serial number with the expression "LOT", where necessary,
e) Expiry date in months and years, where necessary,
f) The phrase "disposable", where necessary,
g) If the device is custom made, the words "custom made device",
h) If the device is intended for clinical investigations, the words "exclusively for clinical investigations"
i) Special storage and/or conditions of use,
j) Special user manual,
k) Any warnings and/or precautions to take,
l) Production date to be specified in the batch/lot or serial number for active medical devices, apart from subparagraph (d),
m) Where applicable, method of sterilisation,
n) With regard to container and medical devices containing radioactive substances, information on permit to be obtained from Turkey Atomic Energy Agency,
o) If the medical device contains a human blood derivative, the related phrase is sought
13.4. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.

13.5. Wherever reasonable and practicable, the medical devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.
13.6. Where appropriate, the instructions for use must contain the following particulars:
a) the details referred to in 13.3, with the exception of d) and e)
b) the performances referred to in section 3 and any undesirable side effects;
c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;
d) all the information needed to verify whether the medical device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the medical devices operate properly and safely at all times;
e) where appropriate, information to avoid certain risks in connection with implantation of the medical device;
f) information regarding the risks of reciprocal interference posed by the presence of the medical device during specific investigations or treatment;
g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilisation;
h) if the medical device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilisation of the medical device to be re-sterilised, and any restriction on the number of reuses. Where medical devices are supplied with the intention that they may be sterilised before use, the instructions for cleaning and sterilisation must be such that, if correctly followed, the medical device will still comply with the requirements in "General Requirements" of this Annex. If the medical device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;
i) details of any further treatment or handling needed before the medical device can be used (for example, sterilisation, final assembly, etc.);
j) in the case of medical devices emitting radiation for medical purpose, details of the nature, type intensity and distribution of this radiation.,
The instructions for use must also include details, allowing the medical staff to brief the patient on any contraindications and any precautions to be taken. These details should cover in particular:
k) precautions to be taken in the event of changes in the performance of the medical device;
l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources etc.:
m) adequate information regarding the medicinal product or products which the medical device in question is designed to administer, including any limitations in the choice of substances to be delivered;
n) precautions to be taken against any special, unusual risks related to the disposal of the medical device;
o) medicinal substances, or human blood derivatives incorporated into the medical device as an integral part in accordance with Section 7.4;
p) degree of accuracy claimed for medical devices with a measuring function;
q) date of issue or the latest revision of the instructions for use.