MEDICAL EQUIPMENTS

Product Code : Bouffant Cap - SMS = CP 0040

Product Code : Surgeon's Cap - SMS = SC 0040

Product Code: Surgeon's Hood - SMS = SH 0040

Product Code : Overshoe - SMS = OS 0040

Product Code : Medic Scrub = MS 0040

Documents :

- **TECHNICAL SHEET**
- **EU DECLARATION OF CONFORMITY**
- **FDA CERTIFICATE**
- **LAB REPORT**
- **TECHNICAL FILE**

Standards :

- **EN 13795 - 1 : 2019**

Preparation date: 14.06.2020

T.013.01	TECHNICAL SHEET
BRAND	BIOBLOCKED
PRODUCT	Bouffant Cap - SMS (NON-STERILE)
PRODUCT CODE	CP 0040

PRODUCT INFORMATION	
Model Description	Head protector with rubber around.
Fabric	40 gr SMS fabric
Material	Number 120 white polyester yarn.
	3 mm rubber

SEWING INSTRUCTIONS, LABEL AND IMPORTANT DETAILS	
General Sewing Instructions	All stitches will be 9 pricks in 2 cm.
	A yellow Groz Beckert needle with a ball tip numbered 9 or 10 will be used. (Gold needle)
	The product is one piece and folded from 3 cm notches and placed on top of each other and the first edge is sewn from 1 cm.
	The second side is folded from 3 cm notches and placed on top of each other and sewn, while 1 cm gap is left from the open side and sewn.
	Starting from the side we left open, the rubber is sewn all around at maximum tension and exit from the other open side.
	Both caps are folded together and sewn again. The excess is arranged with scissors.
	There should be absolutely no thread left on the product.
	After the sewing process is completed, the products will go through 100% quality control.
Labels and Washing Instructions	The information that should be included on the label: BIOBLOCKED logo, disposable, product type, production and expiry date, size, relevant standards, relevant symbols, read the instructions for use, manufacturer company name, chart number and production lot number. The label must be in the language where the product will be shipped or in English.
CAUTION !!!	

PACKAGING DETAILS	
Folding	Work will be performed in accordance with the folding sample, if the folding sample has not reached you, request it.
Bag	Check that it is the same bag used in the folding sample and that the chart is compatible with the specified product code.
	Make sure the bag is closed properly and that there are no tears or holes.
	15x15+5 cm printed bags will be used.
Package	The pieces inside the box should be the same as the ones specified in the chart.
	There should be one size in a box. Sizes should not be mixed.
	Packages should not be broken, collapsed or torn.
	Packages should be closed with tape written bioblocked.

Preparation date: 14.06.2020

T.014.01	TECHNICAL SHEET
BRAND	BIOBLOCKED
PRODUCT	Surgeon's Cap - SMS (NON-STERILE)
PRODUCT CODE	SC 0040

PRODUCT INFORMATION	
Model Description	Head protector with rubber around.
Fabric	40 gr SMS
Material	Number 120 white polyester yarn.
	Spunbond pipe. The cut pipe width will be 2.8 cm. The finished version will be 1 cm.

SEWING INSTRUCTIONS, LABEL AND IMPORTANT DETAILS	
General Sewing Instructions	All stitches will be 9 pricks in 2 cm.
	A yellow Groz Beckert needle with a ball tip numbered 9 or 10 will be used. (Gold needle)
	In the flat machine, the rectangular piece is sewn by folding cleanly from 1 cm on three sides.
	The top is mounted to the round part from 1 cm.
	Right and left bindings are sewn to the ends of the cap.
	Fastening piping length will be 20 cm on the left and right sides.
	There should be absolutely no thread left on the product.
	After the sewing process is completed, the products will go through 100% quality control.
Labels and Washing Instructions	The information that should be included on the label: BIOBLOCKED logo, disposable, product type, production and expiry date, size, relevant standards, relevant symbols, read the instructions for use, manufacturer company name, chart number and production lot number. The label must be in the language the product will be shipped to or in English.
CAUTION !!!	

PACKAGING DETAILS	
Folding	Work will be performed in accordance with the folding sample, if the folding sample has not reached you, request it.
Bag	Check that it is the same bag used in the folding sample and that the chart is compatible with the specified product code.
	Make sure the bag is closed properly and that there are no tears or holes.
	15x15+5 cm printed bags will be used.
Package	The pieces inside the box should be the same as the ones specified in the chart.
	There should be one size in a box. Sizes should not be mixed.
	Packages should not be broken, collapsed or torn.
	Packages should be closed with tape written bioblocked.

T.015.01	TECHNICAL SHEET
BRAND	BIOBLOCKED
PRODUCT NAME	Surgeon's Hood - SMS (NON-STERILE)
PRODUCT CODE	SH 0040

PRODUCT INFORMATION	
Model Description	Surgeon hood with laces and protecting the head and face contour.
Fabric	Main fabric: 40 gr SMS Top piece fabric: 20 gr PP Spunbound.
Material	White polyester yarn number 120
	2.8 cm wide, 30 g Spunbound piping. Lace length will be 30 cm.

SEWING INSTRUCTIONS, LABEL AND IMPORTANT DETAILS	
General Sewing Instructions	All stitches will be 9 pricks in 2 cm.
	A yellow Groz Beckert needle with a 9 or 10 ball tip will be used. (Gold needle)
	The forehead band is combined with a 1 cm stitch allowance on a flat machine.
	20 gr Spunbound top piece is sewn directionally with a 7.5 mm stitch allowance, complying the snaps on the headband.
	The side of the two lace piece that touches the face is pulled and stitched 30 cm longer than the end.
	The back two pieces are stitched together with a 5-thread overlock stitch.
	The back parts are assembled to the front piping piece with 5 thread overlock stitch.
	The top part of the hood is mounted with the body starting from the front notch with straight stitching.
	The front forehead part is folded 5 mm and stitched with 3 mm wide edge stitch.
	There should be absolutely no thread left on the product.
	After the sewing process is completed, the products will go through 100% quality control.
Labels and Washing Instructions	The information that should be included on the label: BIOBLOCKED logo, disposable, product type, production and expiry date, size, relevant standards, relevant symbols, read the instructions for use, manufacturer company name, swatch card number and production lot number. The label must be in the language the product where it will be shipped to or in English.
CAUTION !!!	

PACKAGING DETAILS	
Folding	We will work in accordance with the folding sample, if the folding sample has not reached you, request it.
Bag	Check that it is the same bag used in the folding sample and that the swatch card is compatible with the specified product code.
	Make sure the bag is closed properly and that there are no tears or holes.
	15x15+5cm printed bags will be used.
Package	The amount in the package should be the same as the swatch card.
	There should be one size in a box. Sizes should not be mixed.
	Packages should not be broken, collapsed or torn.
	Packages should be closed with tape written bioblocked.

Preparation date: 14.06.2020

T.016.01	TECHNICAL SHEET
BRAND	BIOBLOCKED
NAME OF THE PRODUCT	Overshoe - SMS (NON-STERILE)
PRODUCT CODE	OS 0040

BIOBLOCKED®

Overshoe – SMS

PRODUCT: OS 0040
PRODUCTION DATE: 15.08.2020
PRODUCTION NUMBER:58771
EXP DATE: 15.08.2023

STD SIZE

EN 13795-1:2019

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

PRODUCT INFORMATION	
Model Description	Shoe protector with wrist elastic.
Fabric	40 gr SMS
Material	Number 120 white polyester yarn.
	3 mm rubber.
	Anti-slip sole.

SEWING INSTRUCTIONS, LABEL AND IMPORTANT DETAILS	
General Sewing Instructions	All stitches will be 9 pricks in 2 cm.
	A yellow Groz Beckert needle with a ball tip numbered 9 or 10 will be used. (Gold needle)
	The notch is centered on the middle of the shoe cover, and the anti-slip tape is sewn with straight stitch both sided.
	Product snap fasteners are folded in half and both heads are sewn with 5 thread overlock.
	The product is turned straight and the ends are well removed.
	From 1 cm below, the rubber is sewn tightly.
	There should be absolutely no thread left on the product.
	After the sewing process is completed, the products will go through 100% quality control.
Label and Washing Instruction	The information that should be included on the label: BIOBLOCKED logo, disposable, product type, production and expiry date, size, relevant standards, relevant symbols, read the instructions for use, manufacturer company name, chart number and production lot number. The label must be in the language the product where it will be shipped or in English.
CAUTION !!!	

PACKAGING DETAILS	
Folding	Work will be performed in accordance with the folding sample, if the folding sample has not reached you, request it.
Bag	Check that it is the same bag used in the folding sample and that the chart is compatible with the specified product code.
	Make sure the bag is closed properly and that there are no tears or holes.
	15x18+5cm printed bags will be used.
Package	The amount in the package should be the same as the chart.
	There should be one size in a box. Sizes should not be mixed.
	Packages should not be broken, collapsed or torn.
	Packages should be closed with tape written bioblocked.

Preparation date: 14.06.2020

T.029.01	TECHNICAL SHEET
BRAND	BIOBLOCKED
PRODUCT	Medic Scrub (NON-STERILE)
PRODUCT CODE	MS 0040

PRODUCT INFORMATION	
Model Description	Surgery gown. Bottom: Elastic waist, back right single pocket. Top: Short sleeve, 3 pockets, V-neck.
Fabric	40 gr SMS
Material	Number 120 white polyester yarn.
	2.5 width rubber.
	SB 2.8 cm wide piping.

SEWING INSTRUCTIONS, LABEL AND IMPORTANT DETAILS	
General Sewing Instructions	All stitches will be 9 pricks in 2 cm.
	A yellow Groz Beckert needle with a ball tip numbered 9 or 10 will be used. (Gold needle)
	The edges of the 3 top pockets are broken from 2 mm and sewn.
	The upper pocket is sewn on the front body at a distance of 20 cm from the arm 9 cm above the arm. Sew the upper and lower pockets according to the model patterns and the original sample.
	The first shoulder is interlaced.
	Collar piling is sewn.
	The second shoulder is interlaced.
	With the open arms, they are sewn by folding at 2 cm.
	It is attached to the body with the arms open.
	Starting from the sleeve hem, side interlace operation is performed.
	Skirts are sewn by folding 3 cm.
	While the trousers are open, the pockets are sewn from the top, which is prepared according to the pattern, and the pocket is sewn from the outside.
	It is sewn from 2 cm while the cuffs are open.
	The front and back crotches are interlaced
	The inner interlace is entered through the left leg and exited from the right leg.
	2.5 cm of rubber is mounted on the belt. The belt is closed by folding inside.
	There should be absolutely no thread left on the product.
	After the sewing process is completed, the products will go through 100% quality control.
Labels and Washing Instructions	The information that should be included on the label: BIOBLOCKED logo, disposable, product type, production and expiry date, size, relevant standards, relevant symbols, read the instructions for use, manufacturer company name, chart number and production lot number. The label must be in the language the product will be shipped or in English.
CAUTION !!!	

PACKAGING DETAILS	
Folding	Work will be performed in accordance with the folding sample, if the folding sample has not reached you, request it.
Bag	Check that it is the same bag used in the folding sample and that the chart is compatible with the specified product code.
	Make sure the bag is closed properly and that there are no tears or holes.
	30x40cm+5 cm printed bags will be used.
Package	The pieces inside the box should be the same as the ones specified in the chart.
	There should be one size in a box. Sizes should not be mixed.
	Packages should not be broken, collapsed or torn.
	Packages should be closed with tape written bioblocked.

EU DECLARATION OF CONFORMITY

YELKENCİ
GROUP

CE

EU DECLARATION OF CONFORMITY

Beyan Ederiz ki;

Aşağıda tanımlanmış olan ürün için 93/42/AT Tıbbi Cihaz Güvenliği Direktifi temel gerekliliklerinin yerine getirildiğini ve sorumluluğun alınmış olunduğunu beyan ederiz. Aşağıda tanımlanan ürünün iç üretimi Yelkenci Hazır Giyim San. ve Tic. A.Ş. tarafından kontrol edilmektedir.

Ürün Adı

BONE - SMS

Tip-Model

CP 0040

Marka

BIOBLOCKED

CE İşaretinin Vurulduğu Yılın Son İki Hanesi

20

Uygulanan AB Yönetmelikleri

AB TIBBİ CİHAZ GÜVENLİĞİ DİREKTİFİ93/42/AT

Uygulanan Standartlar

EN 13795-1 : 2019

We herewith declare;

The undersigned Company declares under its sole responsibility that the item of product specified below satisfies the essential requirements of the Medical Device Safety Directive 93/42/EC which are apply to it. The internal production of the product described below is Yelkenci Hazır Giyim San. ve Tic. A.Ş. controlled by.

Product Name

BOUFFANT CAP - SMS

Type-Models

CP 0040

Brand Name

BIOBLOCKED

Last Two Digit Year of CE marking affixing

20

Applicable EU Directives

MEDICAL DEVICE SAFETY DIRECTIVE 93/42/EC

Applicable Standards

EN 13795-1 : 2019

GENEL MÜDÜR
EREN YELKENCİ
14/05/2020

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

Üretici Firma / Manufacturer Company and Address
YELKENCİ HAZIR GİYİM SANAYİ TİC. A.Ş.
Selimpaşa Mahallesi 5002 Sok. No:6 E-5 Karayolu Üzeri Silivri / İstanbul / Türkiye
Telefon: +90 212 72386 00Web: http://www.yelkenci.comE-mail: sales@yelkenci.com

EU DECLARATION OF CONFORMITY

YELKENCİ
GROUP

CE

EU DECLARATION OF CONFORMITY

Beyan Ederiz ki;

Aşağıda tanımlanmış olan ürün için 93/42/AT Tıbbi Cihaz Güvenliği Direktifi temel gerekliliklerinin yerine getirildiğini ve sorumluluğun alınmış olunduğunu beyan ederiz. Aşağıda tanımlanan ürünün iç üretimi Yelkenci Hazır Giyim San. ve Tic. A.Ş. tarafından kontrol edilmektedir.

Ürün Adı

CERRAH BONESİ - SMS

Tip-Model

SC 0040

Marka

BIOBLOCKED

CE İşaretinin Vurulduğu Yılın Son İki Hanesi

20

Uygulanan AB Yönetmelikleri

AB TIBBİ CİHAZ GÜVENLİĞİ DİREKTİFİ93/42/AT

Uygulanan Standartlar

EN 13795-1 : 2019

We herewith declare;

The undersigned Company declares under its sole responsibility that the item of product specified below satisfies the essential requirements of the Medical Device Safety Directive 93/42/EC which are apply to it. The internal production of the product described below is Yelkenci Hazır Giyim San. ve Tic. A.Ş. controlled by.

Product Name

SURGEON'S CAP - SMS

Type-Models

SC 0040

Brand Name

BIOBLOCKED

Last Two Digit Year of CE marking affixing

20

Applicable EU Directives

MEDICAL DEVICE SAFETY DIRECTIVE 93/42/EC

Applicable Standards

EN 13795-1 : 2019

GENEL MÜDÜR
EREN YELKENCİ
14/05/2020

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

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YELKENCİ
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Ürün Adı

AMELİYAT KAPŞONU - SMS

Tip-Model

SH 0040

Marka

BIOBLOCKED

CE İşaretinin Vurulduğu Yılın Son İki Hanesi

20

Uygulanan AB Yönetmelikleri

AB TIBBİ CİHAZ GÜVENLİĞİ DİREKTİFİ93/42/AT

Uygulanan Standartlar

EN 13795-1 : 2019

We herewith declare;

The undersigned Company declares under its sole responsibility that the item of product specified below satisfies the essential requirements of the Medical Device Safety Directive 93/42/EC which are apply to it. The internal production of the product described below is Yelkenci Hazır Giyim San. ve Tic. A.Ş. controlled by.

Product Name

SURGEON'S HOOD - SMS

Type-Models

SH 0040

Brand Name

BIOBLOCKED

Last Two Digit Year of CE marking affixing

20

Applicable EU Directives

MEDICAL DEVICE SAFETY DIRECTIVE 93/42/EC

Applicable Standards

EN 13795-1 : 2019

GENEL MÜDÜR
EREN YELKENCİ
14/05/2020

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

Üretici Firma / Manufacturer Company and Address
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YELKENCİ
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EU DECLARATION OF CONFORMITY

Beyan Ederiz ki;

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Ürün Adı

AYAKKABI KORUYUCU - SMS

Tip-Model

OS 0040

Marka

BIOBLOCKED

CE İşaretinin Vurulduğu Yılın Son İki Hanesi

20

Uygulanan AB Yönetmelikleri

AB TIBBİ CİHAZ GÜVENLİĞİ DİREKTİFİ 93/42/AT

Uygulanan Standartlar

EN 13795-1 : 2019

We herewith declare;

The undersigned Company declares under its sole responsibility that the item of product specified below satisfies the essential requirements of the Medical Device Safety Directive 93/42/EC which are apply to it. The internal production of the product described below is Yelkenci Hazır Giyim San. ve Tic. A.Ş. controlled by.

Product Name

OVERSHOE - SMS

Type-Models

OS 0040

Brand Name

BIOBLOCKED

Last Two Digit Year of CE marking affixing

20

Applicable EU Directives

MEDICAL DEVICE SAFETY DIRECTIVE 93/42/EC

Applicable Standards

EN 13795-1 : 2019

GENEL MÜDÜR
EREN YELKENCİ
14/05/2020

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

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EU DECLARATION OF CONFORMITY

YELKENCİ GROUP

CE

EU DECLARATION OF CONFORMITY

Beyan Ederiz ki;

Aşağıda tanımlanmış olan ürün için 93/42/AT Tıbbi Cihaz Güvenliği Direktifi temel gerekliliklerinin yerine getirildiğini ve sorumluluğun alınmış olunduğunu beyan ederiz. Aşağıda tanımlanan ürünün iç üretimi Yelkenci Hazır Giyim San. ve Tic. A.Ş. tarafından kontrol edilmektedir.

Ürün Adı

Medikal Giysi - SMS

Tip-Model

MS 0040

Marka

BIOBLOCKED

CE İşaretinin Vurulduğu Yılın Son İki Hanesi

20

Uygulanan AB Yönetmelikleri

AB TIBBİ CİHAZ GÜVENLİĞİ DİREKTİFİ 93/42/AT

Uygulanan Standartlar

EN 13795-1 : 2019

We herewith declare;

The undersigned Company declares under its sole responsibility that the item of product specified below satisfies the essential requirements of the Medical Device Safety Directive 93/42/EC which are apply to it. The internal production of the product described below is Yelkenci Hazır Giyim San. ve Tic. A.Ş. controlled by.

Product Name

MEDİC SCRUB - SMS

Type-Models

MS 0040

Brand Name

BIOBLOCKED

Last Two Digit Year of CE marking affixing

20

Applicable EU Directives

MEDICAL DEVICE SAFETY DIRECTIVE 93/42/EC

Applicable Standards

EN 13795-1 : 2019

GENEL MÜDÜR
EREN YELKENCİ
14/05/2020

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

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Telefon: +90 212 72386 00Web: http://www.yelkenci.comE-mail: sales@yelkenci.com

İstanbul-Türkiye / 26.03.2020_R:0

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:	**CAP, SURGICAL**
Product Code:	**FYF**
Regulation Number:	**878.4040**
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
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info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: August 10, 2020

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:	**COVER, SHOE, OPERATING-ROOM**
Product Code:	**FXP**
Regulation Number:	**878.4040**
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.

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Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
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info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: August 10, 2020

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:	**NON-SURGICAL ISOLATION GOWN**
Product Code:	**OEA**
Regulation Number:	**878.4040**
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

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

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

TEST REPORT
DENEY RAPORU

20019403-Ing-RER
07-20

Customer name:	YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Address:	Selimpaşa Mah. 5001. Sokak No:6 SİLİVRİ/ İSTANBUL
Buyer name:	-
Contact Person:	GÜRSEL ÖZCANLI
Order No:	-
Article No:	SG 0040
Name and identity of test item:	Blue non-woven SMS surgical gown. (BLUE SMS)
The date of receipt of test item:	16.06.2020
Re-submitted/re-confirmation date:	-
Date of test:	16.06.2020-25.06.2020
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	Not Specified
Number of pages of the report:	7

TESTED BY Seal TEST EDİLMİŞTİR

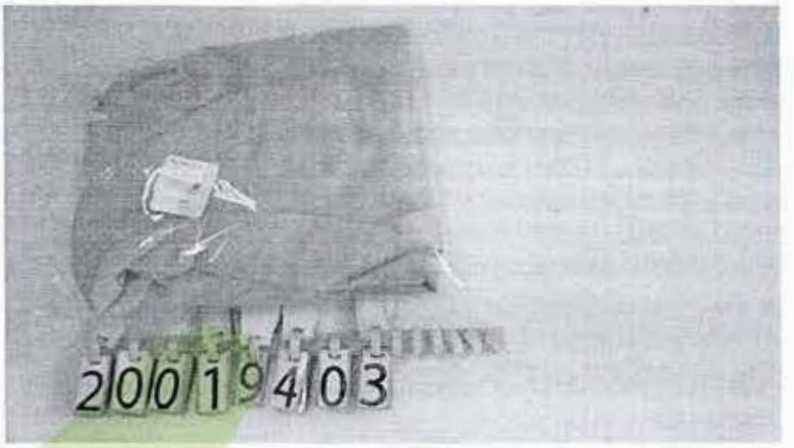
Date	***Customer Representative***	***Head of Testing Laboratory***
02.07.2020	Özlem [illegible]	Sevim A. RAZAK

REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
Dry-Bacterial Penetration[1]	P	
PHYSICAL PROPERTIES TESTS		
Tensile Stregth / **Dry**	P	
Tensile Stregth / **Wet**	P	
Bursting Strength / **Dry**	P	
Bursting Strength / **Wet**	P	
Water Permeability	P	

P: Pass
F: Fail
R: Refer to retailer technologist.
Test results were evaluated according to EN 13795-1:2019 Standard Performance Properties Critical Sample Group limit values (Table 1)
[1] This report was reissued to add this test result.

Gen.f136-2/03

REMARK: Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified.If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2, providing a level of confidence of approximately 95 %. Tests marked (*) in this report are not included in the accreditation schedule.



TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL CLOTHING AND DRAPES –REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DRAPES (*);

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: Ref: EN ISO 11737-1:2018 (*)

The sample is put in extraciton liquid after shaking well, inoculated on the agar.
After incubation at 30 ± 1 ° C for 72 hours, growth microorganisms are counted on the agar.

	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/g)	98 cfu/g	≤300 cfu/g Type I and Type II mask

TEST RESULT

Test Method: BS EN 22610: 2006 (Surgical drapes, garments and fresh air clothes used as medical devices for patients, hospital staff and equipment - Test method for determination of resistance to wet bacterial permeability) (*)

A test sample is placed on the agar plate on a rotating disc. Bacteria carrier material and coating film are placed on the test sample and all parts are fixed on the disk. A finger is placed on the test sample to apply a certain force (3N ± 0.02). The finger moves on the test sample over the entire surface of the agar within 15 minutes. 5 studies are carried out for 15 minutes. 6. The study is repeated by inverting the sample.

Sample amount:	5 pieces 25x25cm2
Carrier Material:	30 µm thin, 25x25cm2 Polyurethane Film
Coating Material:	25x25cm2 HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / ml):	1-4x104 kob / ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		**Penetration Rate**	
X_1	0	R_{CUM1}	0
X_2	0	R_{CUM2}	0
X_3	0	R_{CUM3}	0
X_4	102	R_{CUM4}	0.22
X_5	246	R_{CUM5}	0.46
Z	458		
T	458		

X1 ..... X5: Number of colonies growing in 5 parallel petri in the same sample
Z: number of colonies growing in the sixth petri dish
T: $X_1 + X_2 + X_3 + X_4 + X_5 + Z$

$R_{CUM1} = X1/T$
$R_{CUM2} = (X2 + X1)/T$
$R_{CUM3} = (X3 + X2 + X1)/T$
$R_{CUM4} = (X4 + X3 + X2 + X1)/T$
$R_{CUM5} = (X5 + X4 + X3 + X2 + X1)/T$

BARRIER INDEX (I_B)		
	Result	**Expected value (*)**
I_B	5.31	≥2,8

$I_B = 6 - (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)$

** EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.*

TEST RESULT

TENSILE STRENGTH; EN 29073-3:1996 (*)

Instron 5969 (Load: 50 kN), Strip Method.
Speed: 100 mm/min±10, Gauge length 200 mm.
Pre-load was not applied. Without wetting samples.
The average results are given for weft and warp direction of five samples
Performed in the conditioned room (20±2°C-65%±4).
Dry ;

	RESULT	REQUIREMENT
Weft	61.2 N	≥ 20N (Dry)
Warp	104.8 N	≥ 20N (Dry)

TENSILE STRENGTH; EN 29073-3:1996 (*)

Instron 5969 (Load: 50 kN), Strip Method.
Speed: 100 mm/min±10, Gauge length 200 mm.
Pre-load was not applied. With wetting samples.
The average results are given for weft and warp direction of five samples
Performed in the conditioned room (20±2°C-65%±4).
Wet ;

	RESULT	REQUIREMENT
Weft	59.9 N	≥ 20N (Wet)
Warp	97.4 N	≥ 20N (Wet)

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
Rate of increase in volume; 29 cm^3/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Dry ;	171.5 kPa	≥ 40 kPa (Dry)
Height at Burst*	11.6 mm	

TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL CLOTHING AND DRAPES –REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DRAPES (*);

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
Rate of increase in volume; 45.2 cm^3/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Wet ;	145.2 kPa	≥ 40 kPa (Wet)
Height at Burst*	10.7 mm	

WATER PERMEABILITY;; ISO 811:2018

Hydrostatic Head Tester, Textest marka Fx 3000 model
Temperature of water 20°C. Pressure increase ratio 10 mbar/min.
Performed in the conditioned room (20±2°C-65%±4)

	RESULT	REQUIREMENT
Sample 1	34.3 cmSS	≥ 20cmSS
Sample 2	33.9 cmSS	
Sample 3	31.1 cmSS	
Sample 4	30.8 cmSS	
Sample 5	30.1 cmSS	
Average	32.0 cmSS	

Test Method: ISO 22612: 2005 (Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration)

Samples and containers are sterilized. Agar plates are placed in each container. Samples are placed aseptically in the apparatus. The covers are closed. After making a pot in the sample with the piston, the pistons are removed and 0.5 g ± 0.1 g are added to five samples from the powder contaminated with bacteria and the six to the non-contaminated powder. Then all openings are closed with a plastic bag. The device is operated to give 20,800 vibrations per minute. The test time is 30 minutes. After the test is over, all agar plates are incubated at 35 ° C for 24 hours.

Sample amount:	6 pieces 20x20 cm^2
Mikroorganism:	*Bacillus subtilis ATCC 9372*
Bacterial concentration (cfu/ml):	$1x10^8$
Incubation conditions:	35°C / 24 hours
RESULTS	
Number of Populationg Bacteria (cfu)	
1	0
2	1
3	0
4	0
5	1
6 (Control)	0
Total	2
Logarithm	0,3
** EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.*	

RESULT	
Result (cfu/g)	**Expected Value**
2	≤300 cfu/g

Gen.f136-2/03

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

TEST REPORT
DENEY RAPORU

20019403-RER-Add
07-20

Müşterinin adı:	YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Adresi:	Selimpaşa Mah. 5001. Sokak No:6 SİLİVRİ/ İSTANBUL
Alıcı firma:	-
İlgili kişi:	GÜRSEL ÖZCANLI
İstek numarası:	SG 0040
Model numarası:	-
Numunenin adı ve tarifi:	Mavi dokusuz yüzey önlük.(MAVİ SMS ÖNLÜK)
Numunenin kabul tarihi:	16.06.2020
İlave numune ve/veya ilave bilgi geliş tarihi:	-
Deneyin yapıldığı tarih:	16.06.2020-25.06.2020
Açıklamalar:	-
Numune alımı:	Bu raporda verilen sonuçlar müşteri tarafından gönderilen numuneye aittir.
Numunenin son kullanımı:	-
Yıkama talimatı:	Belirtilmedi.
Raporun sayfa sayısı:	7

TESTED BY EKOTEKS TEST EDİLMİŞTİR

Mühür

Tarih
02.07.2020

Müşteri Temsilcisi
Özlem ULUS

Laboratuvar Müdürü
Sevim A. RAZAK

İSTENEN TESTLER	SONUÇ	AÇIKLAMA
MİKROBİYOLOJİ TESTLERİ		
Biyoyük Tayini	P	
Islak-Bakteri Penetrasyonu	P	
Kuru-Bakteri Penetrasyonu[1]	P	
FİZİKSEL ÖZELLİK TESTLERİ		
Kopma Mukavemeti / **Kuru**	P	
Kopma Mukavemeti / **Yaş**	P	
Patlama Mukavemeti / **Kuru**	P	
Patlama Mukavemeti / **Yaş**	P	
Su Geçirgenliği	P	

P: Geçer
F: Kalır
R: Alıcı firmanın teknik kişisine başvurunuz
Test sonuçları EN 13795-1:2019 Standart Performans Özellikleri Kritik Numune Grubuna göre değerlendirilmiştir. (Tablo 1)
[1]Bu test sonucu eklendiği için bu rapor tekrar düzenlenmiştir.

NOT: Aksi belirtilmediği taktirde testler ile ilgili kayıtlar 5 yıl, orjinal numuneler 3 ay saklanır. Müşteri tarafından talep edildiğinde, testlere ait ölçüm belirsizliği raporlanır fakat "Geçer/Kalır" değerlendirmesinde ölçüm belirsizliği değeri dikkate alınmaz. Raporlanan belirsizlik, genişletilmiş belirsizlik olup standart belirsizlik kapsam faktörü k=2 kullanılarak elde edilmiştir. Güvenilirlik düzeyi % 95'tir. Bu raporda (*) işaretli deneyler akreditasyon kapsamına dahil değildir.

İmzasız ve mühürsüz raporlar geçersizdir.

TEST SONUÇLARI

TEST METODU: EN 13795-1:2019

CERRAHİ GİYSİ VE ÖRTÜLER –GEREKLİLİKLER VE TEST METOTLARI:

KISIM 1: CERRAHİ GİYSİ VE ÖRTÜLER(*);

MİKROBİYAL TEMİZLİK (BİYOYÜK)

Test Metodu: Ref: EN ISO 11737-1:2018 (*)

Örnek, test çözeltisi içerisine atılarak iyice çalkalanır ve uygun besiyerlerine ekilir. 30±1°C'de 72 saat inkübasyon sonrası agarda oluşan mikroorganizmalar sayılır.

	SONUÇ	İSTENEN
Mikrobiyal Temizlik (kob/100 cm²)	98 kob/100 cm²	≤300 kob/100 cm²

**kob:Koloni oluşturan birim*

TEST SONUÇLARI

Test Metodu: BS EN 22610:2006 (Hastalar, hastane personeli ve donanım için tıbbi cihaz olarak kullanılan cerrahi örtüler, giysiler ve temiz hava giysileri - Islak bakteriyel geçirgenliğe olan direncin tayini için deney yöntemi) (*)

Dönen bir disk üzerindeki agar plakasına bir test örneği konur. Test örneğinin üzerine bakteri taşıyıcı materyali ve kaplama filmi yerleştirilir ve bütün parçalar disk üzerinde sabitlenir. Test örneğine belirli bir kuvvet (3N ±0,02) uygulamak üzere bir parmak yerleştirilir. Parmak, 15 dakika içinde agarın tüm yüzeyi boyunca test örneği üzerinde hareket eder. 15 dakikalık 5 çalışma yapılır. 6. çalışma numune ters çevrilerek tekrarlanır.

Numune miktarı :	5 adet 25x25cm²
Taşıyıcı Materyal:	30 µm inceliğinde , 25x25cm² Poliüretan Film
Kaplama Materyali:	25x25cm² HDPE Film
Mikroorganizma:	Staphylococcus aureus ATCC 29213
Bakteri Konsantrasyonu (kob/ml) :	1-4x10⁴ kob/ml
İnkübasyon Koşulları:	(36±1)°C 48 saat

SONUÇLAR			
Nüfus Eden Bakteri Sayısı (cfu)		**Nüfus Etme Oranı**	
X_1	0	R_{CUM1}	0
X_2	0	R_{CUM2}	0
X_3	0	R_{CUM3}	0
X_4	102	R_{CUM4}	0.22
X_5	246	R_{CUM5}	0.46
Z	458		
T	458		

X_1 ..... X_5 : Aynı numunedeki 5 paralel petride üreyen koloni sayısı
Z : altıncı petride üreyen koloni sayısı

T: $X_1 + X_2 + X_3 + X_4 + X_5 + Z$
$R_{CUM1} = X1/T$
$R_{CUM2} = (X2 + X1)/T$
$R_{CUM3} = (X3 + X2 + X1)/T$
$R_{CUM4} = (X4 + X3 + X2 + X1)/T$
$R_{CUM5} = (X5 + X4 + X3 + X2 + X1)/T$

BARİYER İNDEKSİ (I_B)		
	Sonuç	**İstenen (*)**
I_B	5.31	≥2,8

$I_B = 6 - (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)$

** EN 13795-1:2019 Cerrahi giysi ve örtüler - Gereklilikler ve test yöntemleri Tablo-1'e göre değerlendirilmiştir.*

Gen.f136-1/03

TEST SONUÇLARI

TEST METODU: EN 13795-1:2019

CERRAHİ GİYSİ VE ÖRTÜLER –GEREKLİLİKLER VE TEST METOTLARI:

KISIM 1: CERRAHİ GİYSİ VE ÖRTÜLER(*);

KOPMA MUKAVEMETİ; EN 29073-3:1996 (*)

İnstron 5969 (Yük: 50 kN), Şerit Metodu.
Hız: 100 mm/dk±10, Çene mesafesi 200 mm.
Ön gerilme uygulanmamıştır. Islatma işlemi yapılmamıştır.
Atkı ve Çözgü yönlerinde 5 adet sonucun ortalaması verilmiştir.
Kondüsyon şartlarında test edilmiştir. (20±2°C - %65±4)
Kuru;

	SONUÇ	İSTENEN
Atkı	61.2 N	≥ 20N (Kuru)
Çözgü	104.8 N	≥ 20N (Kuru)

KOPMA MUKAVEMETİ; EN 29073-3:1996 (*)

İnstron 5969 (Yük: 50 kN), Şerit Metodu.
Hız: 100 mm/dk±10, Çene mesafesi 200 mm.
Ön gerilme uygulanmamıştır. Islatma işlemi yapılmıştır.
Atkı ve Çözgü yönlerinde 5 adet sonucun ortalaması verilmiştir.
Kondüsyon şartlarında test edilmiştir. (20±2°C - %65±4)
Yaş;

	SONUÇ	İSTENEN
Atkı	59.9 N	≥ 20N (Yaş)
Çözgü	97.4 N	≥ 20N (Yaş)

PATLAMA MUKAVEMETİ; ISO 13938-1:1999

SDL ATLAS M229 Test cihazı. Test alanı 30.5 mm çap
Hacim artış oranı: 29 cm^3/dakika
5 adet sonucun ortalaması verilmiştir.
Kondüsyon şartlarında test edilmiştir (20±2°C-65%±4).

	SONUÇ	İSTENEN
Kuru ;	171.5 kPa	≥ 40 kPa (Kuru)
Şişirme mesafesi*	11.6 mm	

TEST SONUÇLARI

TEST METODU: EN 13795-1:2019

CERRAHİ GİYSİ VE ÖRTÜLER –GEREKLİLİKLER VE TEST METOTLARI:

KISIM 1: CERRAHİ GİYSİ VE ÖRTÜLER(*);

PATLAMA MUKAVEMETİ; ISO 13938-1:1999

SDL ATLAS M229 Test cihazı. Test alanı 30.5 mm çap
Hacim artış oranı: 45.2 cm^3/dakika
5 adet sonucun ortalaması verilmiştir.
Kondüsyon şartlarında test edilmiştir (20±2°C-65%±4).

	SONUÇ	İSTENEN
Yaş;	145.2 kPa	≥ 40 kPa (Yaş)
Şişirme mesafesi*	10.7 mm	

SU GEÇİRGENLİĞİ; ISO 811:2018

Hidrostatik Başlık Cihazı, Textest marka Fx 3000 model
Su sıcaklığı 20°C. Basınç artış oranı 10 mbar/dk.
Kondüsyonlu ortamda test edilmiştir. (20±2°C-65%±4).

	SONUÇ	İSTENEN
Numune 1	34.3 cmSS	≥ 20cmSS
Numune 2	33.9 cmSS	
Numune 3	31.1 cmSS	
Numune 4	30.8 cmSS	
Numune 5	30.1 cmSS	
Ortalama	32.0 cmSS	

TEST SONUÇLARI

Standart Adı: ISO 22612 : 2005 (Enfeksiyöz ajanlara karşı koruyucu giysiler - Kuru mikrobiyal penetrasyona karşı direnç için test yöntemi)
Numuneler ve konteynerler steril edilir. Her bir konteynere agar plakaları konulur. Numuneler aseptik bir şekilde aparata yerleştirilir. Kapaklar kapatılır. Piston ile numunede bir potluk yapıldıktan sonra pistonlar çıkarılır ve beş adet numuneye bakteri ile kontamine edilmiş pudradan, altıncıya ise kontamine olmamış pudradan kontrol olarak 0,5 g ± 0,1 g eklenir. Ardından tüm açıklıklar plastik bir poşetle kapatılır. Dakikada 20.800 titreşim verecek şekilde cihaz çalıştırılır. Test süresi 30 dakikadır. Test bittikten sonra tüm agar plakaları 35°C'de 24 saat inkübe edilir.

Numune miktarı:	6 adet 20x20 cm^2
Mikroorganizma:	*Bacillus subtilis ATCC 9372*
Bakteri Konsantrasyonu (kob/ml):	$1x10^8$
İnkübasyon Koşulları:	35°C / 24 saat
SONUÇLAR	
Nüfuz Eden Bakteri Sayısı (kob)	
1	0
2	1
3	0
4	0
5	1
6 (Kontrol)	0
Toplam	2
Logaritma	0.3
**EN 13795:2011 Cerrahi giysiler ve örtüler – Gereklilikler ve Deney Yöntemleri Bölüm 1: Cerrahi Örtüler ve önlükler Tablo 1'e göre değerlendirilmiştir.*	
SONUÇ	
Sonuç (kob/gr)	**Beklenen Değer**
2	≤300 kob/gr

Gen.f136-1/03

TABLE OF CONTENTS-ABOUT THE GUIDE

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-11**), 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 Control Representative GÜRSEL ÖZCANLI	Company Director 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 13795-1: 2019 Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns

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 Protective Clothing, 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 Surgical Clothing and Drapes, 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.

Company Name: *YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ*

Production Place Address: E5 Karayolu Üzeri 5001. Sokak No:6 Selimpaşa Silivri İSTANBUL

2. REFERENCED STANDARD AND/OR DOCUMENTS

In this manual, reference is made to other standards and / or other documents, with or without a date. These references are indicated at appropriate places in the text and are listed below.

EN,ISO,IEC etc.NO	NAME
EN 13795-1	Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
EN ISO 22612	Microbial penetration — Dry
EN ISO 22610	Microbial penetration — Wet
EN ISO 11737-1	Cleanliness microbial/Bioburden
EN ISO 13938-1	Bursting strength — Dry/Bursting strength — Wet
EN 29073-3	Tensile strength — Wet/Tensile strength — Dry
EN ISO 13688	Protective Clothing - General Features

3. Product Information

3.1 Product Description

Protective Clothing (Medic Scrub,Overshoe, Surgeon's Hood, Surgeon's Cap, Bouffant Cap) that we manufacture have a suitable microbial barrier, which aims to limit the transmission of infective agents between personnel and patients during surgical procedures and in other medical environments with similar

requirements. It can be effective in reducing the spread of infective agents in asymptomatic carrier or patient with clinical symptoms, our company produces Protective Clothing with these features in a high quality and hygienic environment.

2 Brand Name: BIOBLOCKED

3.3 Product Model No:

MS 0040 Medic Scrub
CP 0040 Bouffant Cap - SMS
SC 0040 Surgeon's Cap - SMS
SH 0040 Surgeon's Hood - SMS
OS 0040 Overshoe - SMS

3.4 Product Dimension:

OS 0040, SH 0040, SC 0040, CP 0040 = One size.
MS 0040 Medic Scrub = S-M-L-XL-XXL-XXXL

3.5 Factory Production Control:
The documentation of the manufacturing control system is designed to ensure that the quality assurance is widely understood, to ensure that the required product properties are provided and to control the effective operation of the manufacturing control system.

3.6 Materials and Intermediates Used

NO	MATERIAL USED	SPECIFICATION	MANUFACTURER INFORMATION
1	FABRIC	SMS Fabric 40 gr	Gülsan Tekstil
2	SEWING THREAD	Coast 120 Numara İplik	COATS
3	PACKING MATERIAL - BAG	PRINTED BAG	DEKA PLASTİK
4	PARCEL	KSSK QUALITY	MERCAN AMBALAJ
5	Elastic	PRINTED BAG	SANCAK ÖRME
6	Wigan Non-Slip Fabric	KSSK QUALITY	Mahmut Tekstil
7	Waist Elastic	2.5 cm Waist Elastic	SANCAK ÖRME

Since SMS fabric used in SG 0040 product was used in the specified 5 products, a technical file was created based on the test report no. 20019403 of Ekoteks Labaratuvar ve Gözetim Hizmetleri A.Ş.

3.7 Product Photos (Appendix A)
3.8 Marking (Annex B)
3.9 Instructions for Use (Annex C)
3.10 Essential Health and Safety Requirements Fulfilled by the Product (Annex D)
3.11 Essential Health and Safety Requirements Fulfilled by the Product (Annex E)
3.12 Machinery and equipment used in the production of the product;

- Flat Machine
- Overlock Machine
- Cutting Engine
- Marker Table

- Modelroom Mold Drawing Machine
- Cutter Cutting Machine (for narrow fabrics)

3.13 Stitch Joining Section

All stitches are made with 5 thread overlock stitch. A single needle sewing machine is used for sewing elastics, laces, labels and non-slip tapes.

4. REQUIREMENTS

4.1 MANUFACTURING CONTROL

Technical File - Manufacturing Control Guide is the continuous internal control of manufacturing processes. This system includes the requirements for the controls performed to ensure the above-defined Protective Clothing with the performance declared in the EU Type Approval Certificate.

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

Our company has established a Manufacturing Control system to guarantee that the product supplied to the market is in accordance with the specified specifications, has started certification studies and maintains this system. The Manufacturing Control system includes operations, regular inspections, tests and/or evaluations, and the use of results for the control of raw and other input materials or components, the manufacturing processes of equipment and the product.

4.2 QUALITY PLAN

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

-The organizational structure of the manufacturer regarding suitability and quality
Document control
- Control procedures regarding the components and the product supplied
-Process control
- Conditions in the transportation and storage of the product,
- Requirements for inspection and testing of processes and products
-Methods to be applied in case of non-conformity

4.3 ORGANIZATION

4.3.1 Responsibility and Authority

The responsibility, authority and relationship between all personnel who manage, do and approve the works affecting conformity and quality are defined in the quality plan. While making the definition, the personnel authorized for the following issues are specified.

- Starting a process to prevent the production of non-conforming products,
-Defining and recording any quality problems 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 inspection and Quality Plan requirements. This representative can perform supervision and surveillance work alone.

REFERENCE

Management Representative Appointment Letter

4.3.3 Internal audits

Our company conducts internal audits to verify that the works are in accordance with the planned regulations and to determine the effectiveness of Manufacturing Control. The audits are scheduled

according to the importance and condition 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 personnel who have responsibility in the field of audit. The personnel responsible for this area keeps records of the measures taken by taking timely measures when there is a non-conformity during the inspections.

REFERENCE
Internal Audit Procedure
Non-conforming Product Control Procedure
Corrective and Preventive Actions Procedure

4.3.4 Management Review

The Manufacturing Control system is reviewed annually by the management to ensure its continuity and effectiveness, and relevant records are kept.

REFERENCE
MR Meeting Minutes

4.3.5 Subcontractor Services

Our company does not supply any subcontracting services other than its own resources, and in case of such a situation, a control method will be established and this application will be a part of our company's quality control procedures.

4.4 Document Control

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

REFERENCE
Document Control Procedure

Records Control Procedure

5 CONTROL METHODS

5.1 Component Materials

Sufficient component materials are kept ready to ensure that manufacturing and distribution are carried out at the planned speeds, so as not to adversely affect the conformity of the product.

In order to ensure compliance of Protective Clothing (Overalls), specifications and tolerances have been created for the necessary component materials used in production and these are notified to the supplier in writing.

These checks verify that input material suppliers are able to ensure the required quality of materials and conform to the EU Type Approval Certificate.

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 Customer supplied product

No component material to be used in Protective Clothing supplied by the customer is not used, and in such a case, the necessary conditions will be provided by our company.

5.3 Operations control

The quality plan includes the following issues.

a) Conformity with all inputs used with the type-approved protype

b) The suitability of the cutting process (coming together of the same pieces from the same lot)

c) Stitch control, stitch step density control, stitch type control, sealing tape control used in seams, if any

d) Size control

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

f) Label user manual and packaging control

5.4 Transport, Storage and Distribution

It includes the procedures that will ensure the hygiene rules during the transportation and storage of Surgical Garments and Covers.

REFERENCE
Transport, Storage, Storage and Shipping instruction

6 INSPECTION AND TESTS

6.1 General

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

All inspections performed by quality control personnel are recorded, and if non-conforming products can be separated, the shipment of products that are eliminated by reprocessing is approved.

6.2 Input Component Material
Input component materials are inspected and tested using the detailed procedures specified 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, the necessary inspections of the materials continue.

7 NON-CONFORMITY STATUS

7.1 General
Provided that it is reasonably applicable, our company has documented and ensures its continuity in order to prevent the use and application of the product that does not comply with the specified requirements. This control is necessary for identification evaluation and segregation (where practical) and elimination of non-compliant product. All of the procedures to be carried out are documented and a system has been established to inform the user if the shipment of the inappropriate product cannot be prevented.

Nonconformity may occur in the following stages;
a) In 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 non-conforming materials, products or processes are identified, investigations are initiated to determine the causes of non-conformity and effective corrective measures are applied according to the methods specified in the quality plan to prevent recurrence of the non-conformity.
REFERENCE
Non-conforming product control procedure

7.2 Non-conformity of component materials

In case of non-conforming component materials, corrective measures may be the following;

a) Reprocessing of component materials
b) Adjusting manufacturing control to separate non-conforming components
c) Rejection and elimination of unsuitable material.

REFERENCE

Non-conforming product control procedure

7.3 Non-conformity of the final, finished product (from the result of the examination of the operations performed)

Non-conforming Protective Clothing (Overalls) are evaluated and necessary methods are followed to take corrective measures. Some measures consist of the following:

a) If the non-conforming product is applicable, re-processing and acceptance of its shipment,
b) If reprocessing is not applicable, directing to alternative use,
c) Rejection of the product,

REFERENCE

Non-conforming product control procedure
Quality plan

8 Records

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

In cases where the component material or Protective Clothing that is being worked on does not meet the specification requirements, the corrective measures taken to ensure the product quality of the materials are recorded.

Records are archived and retained for a period of at least 5 years in a reproducible form or for a longer period as required by country legislation.

REFERENCE

Sample Label
Analysis Reports
Quality Records Control Procedure

9 Training

Our company has established and implemented methods for the training of all personnel involved in the work that affects the quality. Personnel taking on specific tasks have appropriate quality and expertise based on appropriate education, training or experience as required. Training records are kept.

Note- Although a demonstrable training may be needed for the implementation of the quality mark, as per the legislation, marking is related to the compliance of the product with the performance characteristics using only written procedures. Therefore, although it may be necessary to use "expert" personnel in marking as required by the legislation, a training requirement that needs to be proven especially for expertise is not sought.

REFERENCE

Training records

Annex A

PRODUCT PHOTOS

MODEL NO : MS 0040

MODEL NO : OS 0040

MODEL NO : SC 0040

MODEL NO : SH 0040

MODEL NO : CP 0040

Labels;

BIOBLOCKED®

Bouffant Cap - SMS

PRODUCT: CP 0040
PRODUCTION DATE: 24.09.2020
PRODUCTION NUMBER:58770
EXP DATE: 24.09.2023

STD SIZE

EN 13795-1:2019

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

BIOBLOCKED®

Medic Scrub

PRODUCT: MS 0040
PRODUCTION DATE: 24.09.2020
PRODUCTION NUMBER:10031
EXP DATE: 24.09.2023

L

EN 13795-1:2019

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

BIOBLOCKED®

Overshoe - SMS

PRODUCT: OS 0040
PRODUCTION DATE: 15.08.2020
PRODUCTION NUMBER:58771
EXP DATE: 15.08.2023

STD SIZE

EN 13795-1:2019

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

BIOBLOCKED®

Surgeon's Cap - SMS

PRODUCT: SC 0040
PRODUCTION DATE: 24.09.2020
PRODUCTION NUMBER:58772
EXP DATE: 24.09.2023

STD SIZE

EN 13795-1:2019

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

BIOBLOCKED®

Surgeon's Hood - SMS

PRODUCT: SH 0040
PRODUCTION DATE: 24.09.2020
PRODUCTION NUMBER:58773
EXP DATE: 24.09.2023

STD SIZE

EN 13795-1:2019

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.

Annex B

MARKING

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET AŞ
E5 Karayolu üzeri 5001 sk. No:6 Selimpasa- Silivri - ISTANBUL / TURKIYE

EN 13795-1:2019

13.3. Information that should be included on the label:
a) The name or commercial name and address of the manufacturer, for imported medical devices, as well as the name or commercial name and address of the authorized representative and / or importer must be included on the label or in the sales package or in the user manual.
b) Detailed information that defines the contents of the packaging and the medical device and especially for the user,
c) When necessary, the phrase "STERILE",
ç) When necessary, batch code or serial number with the expression "LOT",
d) If necessary, the expiry date in month and year,
e) When necessary, the phrase "for single use",
f) If the medical device is made on order, the phrase "It is a custom-made device",
g) The phrase "For Clinical Research" in clinical research devices,
ğ) Special storage and / or usage conditions,
h) Special user manual,
ı) Warnings and / or measures to be taken,
i) For active medical devices, the date of manufacture to be specified in the batch / lot or serial number, apart from sub-paragraph (d),
j) When required, the method of sterilization,
k) With regard to container and medical devices containing radioactive substances, information on Turkey Atomic Energy Agency permit to be obtained from,

l) If the medical device contains a human blood derivative, the statement stating this is sought.

Annex C

USAGE INSTRUCTIONS

CE

ISO 9001:2015
ISO 14001:2015
ISO 13485:2016
ISO 22716:2007

EN13795-1:2019

BioBlocked.com

ENGLISH

PRODUCT FEATURES

- SMS Fabric
- Non-Sterile.
- Top ; V-neck, short sleeves, 3 pockets, side slit.
- Trousers ; Elastic waist, 1 back pockets, classic leg.

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- SMS Kumaş
- Steril değildir.
- Üst Forma ; V yakalı, kısa kollu, 3 cepli, yanları yırtmaçlı.
- Pantolon ; Beli bütün lastikli, 1 arka cep, klasik paça.

ENGLISH

INSTRUCTION FOR REMOVAL

- Remove the garment by turning it inside out avoiding as much contact as possible
- Use disinfectant should there be no soap and water available.

TÜRKÇE

ÖNLÜK NASIL ÇIKARILIR ?

- Mümkün olduğunca fazla temastan kaçınarak giysiyi ters çevirerek çıkarın.
- Sabun ve su olmadığında dezenfektan kullanın.

ENGLISH

Storage / Final Use
It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date.

Destruction / Recycling
The uncontaminated products can be treated as general waste or can be recycled. Contaminated products should be treated as hazardous wastes and should be disposed of in accordance with the rules laid down by law.

Manufacturer: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Eşkinoşo Mahallesi Mh. 5001 Sk. No: 6/A Silivri/İstanbul

TÜRKÇE

Saklama / Son Kullanım
Karton veya mukavva kutu içerisinde; güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

İmha / Geri Dönüşüm
Bulaşma olmamış ürünler genel çöp olarak işlem görebilir veya geri dönüştürülebilir. Bulaşma olmuş ürünler ise zararlı atıklar olarak işlem görmesi ve yasanın belirttiği kuallar uyarınca atılması gerekir.

Üretici: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Eşkinoşo Mahallesi Mh. 5001 Sk. No: 6/A Silivri/İstanbul

SAFETY INSTRUCTION
All protective clothes should be checked for defects like cuts, holes, rips and contamination. Don't use if garment is detected.

GÜVENLİK TALİMATI
Bütün koruyucu giysiler, kullanmadan önce, yırtık, delik, sökük, kir gibi olumsuzluk delo ve arızalara karşı kontrol edilmelidir. Defolu ve kirli ise kesinlikle giyilmemelidir.

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiés avant utilisation contre les défauts et les imperfections pouvant causer une défaillance à l'utilisation comme un trou, une déchirure ou saleté . Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

SICHERUNGSANWEISUNG
Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft werden, die Risse, Löche, Zerissen, Schmutz usw. verursachen können. Wenn es fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

ATTENTION!
This bag is not a toy. It may cause suffocation. Please keep it away from children and infants.

DİKKAT!
Poşet ile oynamak tehlikelidir, boğulmaya sebep olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

ATTENTION!
Le vêtement est emballé dans un sac. Jouer avec un sac est dangereux et peut provoquer un étouffement. Gardez-le à l'écart des enfants et des nourissons.

ACHTUNG!
Das Spielen mit dem Beutel ist gefährlich und kann zum Ersticken führen. Bitte halten Sie es von Kindern und Babys fern.

DISPOSABLE GARMENT | **TEK KULLANIMLIK GİYSİ** | **VÊTEMENT JETABLE** | **EINWEGBARE BEKLEIDUNG**

Product: MS 0040

BIOBLOCKED®

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

ENGLISH

HOW TO WEAR ?

- The overshoe are opened with both hands to allow the shoes to enter the overshoe easily.

HOW TO REMOVE ?

- It should be removed by sitting.
- In removal, should be careful to remove the over shoe by inverting.
- The rubbers are widened to remove the back side of the shoe and then the front side.
- Hands are washed with soap after this process. Disinfectant should be used at times when there is no water and soap.

TÜRKÇE

NASIL GİYİLİR ?

- Lastiği iki elle açılarak ayakkabının rahat bir şekilde ürünün içine girmesi sağlanılır.

NASIL ÇIKARTILIR ?

- Oturularak çıkarılmalıdır.
- Çıkarma işleminde galoşun ters çevrilerek çıkarılmasına dikkat edilmelidir.
- Lastikler genişletilerek ayakkabının önce arka tarafı sonra ön tarafının çıkarılması sağlanılır.
- Eller bu işlemden sonra sabun ile yıkanır. Su ve sabun olmadığı zamanlarda dezenfektan kullanılmalıdır.

ENGLISH

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date.

Destruction / Recycling

The uncontaminated products can be treated as general waste or can be recycled. Contaminated products should be treated as hazardous wastes and should be disposed of in accordance with the rules laid down by law.

Manufacturer: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Mahallesi Mah. 5001 Sk. No. 6/A Silivri İstanbul

TÜRKÇE

Saklama / Son Kullanım

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

İmha / Geri Dönüşüm

Bulaşma olmamış ürünler genel çöp olarak işlem görebilir veya geri dönüştürülebilir. Bulaşma olmuş ürünler ise zararlı atıklar olarak işlem görmesi ve yasanın belirttiği kurallar uyarınca atılması gerekir.

Üretici: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Mahallesi Mah. 5001 Sk. No. 6/A Silivri İstanbul

SAFETY INSTRUCTION
All protective clothes should be checked for defects like cuts, holes, rips and contamination. Don't use if garment is defected.

GÜVENLİK TALİMATI
Bütün koruyucu giysiler, kullanmadan önce, yırtık, delik, sökük, kir gibi olumsuzluk defo ve arızalara karşı kontrol edilmelidir. Defolu ve kirli ise kesinlikle giyilmemelidir.

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiés avant utilisation contre les défauts et les imperfections pouvant causer une défaillance à l'utilisation comme un trou, une déchirure ou saleté. Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

SICHERUNGSANWEISUNG
Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft werden, die Risse, Löcher, Zerissen, Schmutz usw. verursachen können. Wenn es fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

ATTENTION!
This bag is not a toy. It may cause suffocation. Please keep it away from children and infants.

DİKKAT!
Poşet ile oynamak tehlikelidir, boğulmaya sebep olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

ATTENTION!
Le vêtement est emballé dans un sac. Jouer avec un sac est dangereux et peut provoquer un étouffement. Gardez-le à l'écart des enfants et des nourissons.

ACHTUNG!
Das Spielen mit dem Beutel ist gefährlich und kann zum Erstickon führen. Bitte halten Sie es von Kindern und Babys fern.

DISPOSABLE GARMENT | **TEK KULLANIMLIK GİYSİ** | **VÊTEMENT JETABLE** | **EINWEGBARE BEKLEIDUNG**

8 682753 521500

Product: OS 0040
Exp. Date: 07/23

BIOBLOCKED®

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

ENGLISH

PRODUCT FEATURES

- SMS Fabric
- Non-Sterile.
- It can be used in all environments that require hygiene.
- Adjustable ties.

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- SMS Kumaş
- Steril değildir.
- Hijyen gerektiren tüm ortamlarda kullanılabilir.
- Ayarlanabilir bağlar.

ENGLISH

HOW TO WEAR ?

- The bonnet is placed on the head, completely covering the hair.
- Laces are tied and the bonnet is fixed.

HOW TO REMOVE ?

- The laces are unfastened. The outer surface is removed from the head with the inside.
- Hands are washed with soap after this procedure. Disinfectant should be used when there is no water and soap.

TÜRKÇE

NASIL GİYİLİR ?

- Bone, saçları tamamen içine alacak şekilde başa yerleştirilir.
- Bağcıklar bağlanarak bone sabitlenir.

NASIL ÇIKARTILIR ?

- Bağcıklar çözülür. Dış yüzeyi içte kalacak şekilde kafadan çıkarılır.
- Eller bu işlemden sonra sabun ile yıkanır.Su ve sabun olmadığı zamanlarda dezenfektan kullanılmalıdır.

ENGLISH

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date.

Destruction / Recycling

The uncontaminated products can be treated as general waste or can be recycled. Contaminated products should be treated as hazardous wastes and should be disposed of in accordance with the rules laid down by law.

Manufacturer: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Merkez Mh. 5001 Sk. No. 6/A Silivri İstanbul

TÜRKÇE

Saklama / Son Kullanım

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

İmha / Geri Dönüşüm

Bulaşma olmamış ürünler genel çöp olarak işlem görebilir veya geri dönüştürülebilir. Bulaşma olmuş ürünler ise zararlı atıklar olarak işlem görmesi ve yasanın belirttiği kurallar uyarınca atılması gerekir.

Üretici: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Merkez Mh. 5001 Sk. No. 6/A Silivri İstanbul

SAFETY INSTRUCTION
All protective clothes should be checked for defects like cuts, holes, rips and contamination. Don't use if garment is detected.

GÜVENLİK TALİMATI
Bütün koruyucu giysiler, kullanmadan önce, yırtık, delik, sökük, kir gibi olumsuzluk defo ve arızalara karşı kontrol edilmelidir. Defolu ve kirli ise kesinlikle giyilmemelidir.

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiés avant utilisation contre les défauts et les imperfections pouvant causer une déchirure ou saleté. Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

SICHERUNGSANWEISUNG
Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft werden, die Risse, Löcher, Zerissen, Schmutz usw. verursachen können. Wenn es fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

ATTENTION!
This bag is not a toy. It may cause suffocation, Please keep it away from children and infants.

DİKKAT!
Poşet ile oynamak tehlikelidir, boğulmaya sebep olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

ATTENTION!
Le vêtement est emballé dans un sac, Jouer avec un sac est dangereux et peut provoquer un étouffement, Gardez-le à l'écart des enfants et des nourrissons.

ACHTUNG!
Das Spielen mit dem Beutel ist gefährlich und kann zum Erstickn führen. Bitte halten Sie es von Kindern und Babys fern.

DISPOSABLE GARMENT | **TEK KULLANIMLIK GİYSİ** | **VÊTEMENT JETABLE** | **EINWEGBARE BEKLEIDUNG**

8 682753 521302

Product: SC 0040

Exp. Date: 07/23

BIOBLOCKED®

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

ENGLISH

PRODUCT FEATURES

- SMS Fabric
- Non-Sterile.
- Surgeons hoods provide head and neck coverage but leave the face exposed and are secured with a tie at the back of the neck.
- Surgeons hoods are recommended for medical use to provide protection against the risk of cross infection between the patient and healthcare prov

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- SMS Kumaş
- Steril değildir.
- Cerrah bonesi baş ve boyun örtüsünü sağlar, ancak yüzü açıkta bırakır ve boynun arkasında bir bağcık ile sabitlenir.
- Cerrah boneleri, hasta ve sağlık kuruluşu arasında çapraz enfeksiyon riskine karşı koruma sağlamak için tıbbi kullanım için tavsiye edilir.

ENGLISH

HOW TO WEAR ?

- The product is wear to cover the ears and cover the hair.
- The laces are tied at the back to cover the neck area.

HOW TO REMOVE ?

- The laces are dissolved. They are removed from the head by holding them in the laces. The outer surface of the product is collected to remain inside.
- Hands are washed with soap after this procedure. Disinfectant should be used when there is no water and soap.

TÜRKÇE

NASIL GİYİLİR ?

- Ürün alını, kulakları kapatacak ve saçları içeri alacak şekilde giyilir.
- Bağcıklar boyun bölgesini kapatacak şekilde arka tarafta bağlanır.

NASIL ÇIKARTILIR ?

- Bağcıklar çözülür.Bağcıklarda tutarak kafadan çıkarılır.Ürünün dış yüzeyi içte kalacak şekilde toplanır.
- Eller bu işlemden sonra sabun ile yıkanır. Su ve sabun olmadığı zamanlarda dezenfektan kullanılmalıdır.

ENGLISH

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date.

Destruction / Recycling

The uncontaminated products can be treated as general waste or can be recycled. Contaminated products should be treated as hazardous wastes and should be disposed of in accordance with the rules laid down by law.

Manufacturer: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Merkez Mh. 5001 Sk. No: 6/A Silivri/İstanbul

TÜRKÇE

Saklama / Son Kullanım

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

İmha / Geri Dönüşüm

Bulaşma olmamış ürünler genel çöp olarak işlem görebilir veya geri dönüştürülebilir. Bulaşma olmuş ürünler ise zararlı atıklar olarak işlem görmesi ve yasanın belirttiği kurallar uyarınca atılması gerekir.

Üretici: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Merkez Mh. 5001 Sk. No: 6/A Silivri/İstanbul

SAFETY INSTRUCTION
All protective clothes should be checked for defects like cuts, holes, rips and contamination. Don't use if garment is defected.

GÜVENLİK TALİMATI
Bütün koruyucu giysiler, kullanmadan önce, yırtık, delik, söküK, kir gibi olumsuzluk defo ve arızalara karşı kontrol edilmelidir. Defolu ve kirli iso kesinlikle giyilmemelidir.

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiés avant utilisation contre les défauts et les imperfections pouvant causer une défaillance à l'utilisation comme un trou, une déchirure ou saleté. Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

SICHERUNGSANWEISUNG
Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft werden, die Risse, Löcho, Zerissen, Schmutz usw. verursachen können. Wenn as fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

ATTENTION!
This bag is not a toy. It may cause suffocation. Please keep it away from children and infants.

DİKKAT!
Poşet ile oynamak tehlikelidir, boğulmaya sebop olabilir. Lütfen çocuk ve bebeklerden uzak tutunuz.

ATTENTION!
Le vêtement est emballé dans un sac. Jouer avec un sac est dangereux et peut provoquer un étouffement. Gardez-le à l'écart des enfants et des nourrissons.

ACHTUNG!
Das Spielen mit dem Beutel ist gefährlich und kann zum Ersticken führen. Bitte halten Sie es von Kindern und Babys fern.

DISPOSABLE GARMENT | **TEK KULLANIMLIK GİYSİ** | **VÊTEMENT JETABLE** | **EINWEGBARE BEKLEIDUNG**

8 682753 521401

Product: SH 0040

Exp. Date: 07/23

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ENGLISH

PRODUCT FEATURES

- SMS Fabric
- Non-Sterile.
- It can be used in all environments that require hygiene.

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- SMS Kumaş
- Steril değildir.
- Hijyen gerektiren tüm ortamlarda kullanılabilir.

ENGLISH

HOW TO WEAR ?

- The bonnet is opened with two hands by its rubbery part.
- The rubber part of the bonnet is placed on the forehead.
- The bonnet is placed on the head, completely covering the hair.

HOW TO REMOVE ?

- The rubber of the bonnet is gripped from the back of the head.
- The rubber is folded in front and the bone is removed.
- Hands are washed with soap after this procedure. Disinfectant should be used when there is no water and soap.

TÜRKÇE

NASIL GİYİLİR ?

- Bone, lastikli kısmından iki elle tulup açılır.
- Bonenin lastikli kısmı alına yerleştirilir.
- Bone, saçları tamamen içine alacak şekilde başa yerleştirilir.

NASIL ÇIKARTILIR ?

- Kafanın arka tarafından bonenin lastiği kavranır.
- Lastik ön tarafa doğru içe katlanarak bone çıkarılır.
- Eller bu işlemden sonra sabun ile yıkanır.Su ve sabun olmadığı zamanlarda dezenfektan kullanılmalıdır.

ENGLISH

Storage / Final Use

It is recommended to keep it in cardboard or cardboard box, away from sunlight, between 15 - 25 °C. If stored under suitable conditions, it is recommended to use it within 3 years after the production date.

Destruction / Recycling

The uncontaminated products can be treated as general waste or can be recycled. Contaminated products should be treated as hazardous wastes and should be disposed of in accordance with the rules laid down by law.

Manufacturer: YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Merkez Mh. 5001 Sk. No. 6/A Silivri İstanbul

TÜRKÇE

Saklama / Son Kullanım

Karton veya mukavva kutu içerisinde, güneş ışınlarından uzak 15 - 25°C arasında muhafaza edilmesi Tavsiye edilir. Uygun koşullarda depolandığı takdirde üretim tarihinden sonra 3 yıl içerisinde kullanılması tavsiye edilir.

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Üretici: YELKENCİ HAZİR GİYİM SANAYİ VE TİCARET A.Ş. Selimpaşa Merkez Mh. 5001 Sk. No. 6/A Silivri İstanbul

SAFETY INSTRUCTION
All protective clothes should be checked for defects like cuts, holes, rips and contamination. Don't use if garment is detected.

GÜVENLİK TALİMATI
Bütün koruyucu giysiler, kullanmadan once, yırtık, delik, sökük, kir gibi olumsuzluk defo ve arızalara karşı kontrol edilmelidir. Defolu ve kirli ise kesinlikle giyilmemelidir.

INSTRUCTION DE SÉCURITÉ
Tous les vêtements de protection doivent être vérifiés avant utilisation contre les défauts et les imperfections pouvant causer une défaillance à l'utilisation comme un trou, une déchirure ou saleté. Si le vêtement est défectueux ou sale, il ne doit pas être porté en l'état.

SICHERUNGSANWEISUNG
Alle Schutzkleidung sollte vor dem Gebrauch auf Defekte und Fehler überprüft werden, die Risse, Löche, Zerissen, Schmutz usw. verursachen können. Wenn es fehlerhaft und schmutzig ist, sollte es nicht getragen werden.

ATTENTION!
This bag is not a toy, It may cause suffocation. Please keep it away from children and infants.

DİKKAT!
Poşet ile oynamak tehlikelidir, boğulmaya sebep olabilir. Lutfen çocuk ve bebeklerden uzak tutunuz.

ATTENTION!
Le vêtement est emballé dans un sac, Jouer avec un sac est dangereux et peut provoquer un étouffement. Gardez-le à l'écart des enfants et des nourrissons.

ACHTUNG!
Das Spielen mit dem Beutel ist gefährlich und kann zum Erstickan führen. Bitte halten Sie es von Kindern und Babys fern.

DİSPOSABLE GARMENT | **TEK KULLANIMLIK GİYSİ** | **VÊTEMENT JETABLE** | **EINWEGBARE BEKLEIDUNG**

8 682753 521203

Product: CP 0040
Exp. Date: 07/23

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SAFETY INSTRUCTIONS: All protective clothing should be checked against defects and malfunctions that may cause adverse effects such as tears, holes, and loose dirt. It should never be worn if it is faulty and dirty.

Caution! It is dangerous to play with the bag, it can cause suffocation. Please keep away from children and babies.

STORAGE/USE BY: It is recommended to keep it in a cardboard or cardboard box, away from sunlight at 15 -25 °C. If stored under appropriate conditions, it should be used within 3 years after the production date.

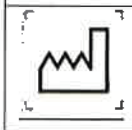
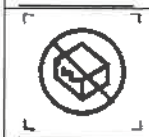
DISPOSAL AND RECYCLING: Uncontaminated products can be treated as general waste or recycled. Contaminated products, on the other hand, must be treated as hazardous wastes and disposed of in accordance with the rules specified by law.

"In case of long-term use in temperate climates and environments, it may cause overheating "

"Flammable material. Keep away from fire."

Disposable, "Do not reuse!"

Meaning of the Symbols on the Product Package

SYMBOL	TITLE OF THE SYMBOL	DESCRIPTION OF THE SYMBOL	SAMPLE
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385 / EEC, 93/42 / EEC and 98/79 / EC.	 Name Address
	Production date	Indicates the date the medical device was manufactured.	 2020 - 06
	Used by	Shows the expiration date of the medical device.	 2021 - 06
	(Non Sterile)	Indicates that a medical device has not been subjected to sterilization.	
	Do not use if the package is damaged.	Indicates that the medical device should not be used if the packaging is damaged or opened.	
	Keep dry	Indicates that the medical device must be protected from moisture.	

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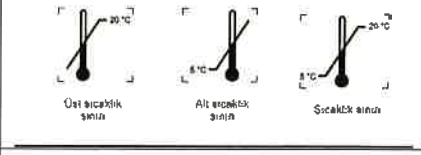
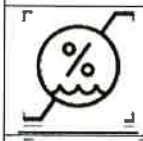
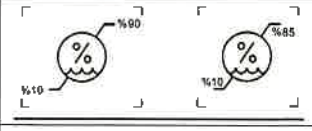
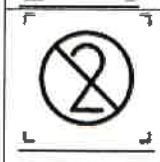
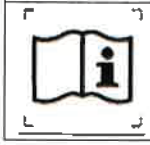
	Temperature limitation	Indicates the temperature limits to which the medical device can be safely exposed.	
	Humidity limitation	Indicates the humidity range to which the medical device can be safely exposed.	
	Do not reuse	Indicates that the medical device is intended for single use or for use on a single patient during a single procedure.	Disposable PPE, "Do not reuse!"
	See instructions for use	It shows that I have to look at the user's instructions for use.	

Annex D

– the general principles governing the biological evaluation of medical devices within a risk management process;
– the general categorization of devices based on the nature and duration of their contact with the body;
– the evaluation of existing relevant data from all sources;
– the identification of gaps in the available data set on the basis of a risk analysis;
– the identification of additional data sets necessary to analyse the biological safety of the medical device;
– the assessment of the biological safety of the medical device.

Hazardous Substance Safety Data Sheets (MSDS) are identified and evaluated by all of our suppliers, whose processes, the risk management plan has identified and assigned the biological assessment issues that require specific technical qualifications, and the person (s) responsible for biological safety assessment. (ISO 10993)

ANNEX - E

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.