BIOBLOCKED®

SG 0240 SURGICAL GOWN REINFORCED

Various gowns and drapes for any kind of professional usage in health sector.
Designed and produced with health workers in mind.

Surgical Gowns - Reinforced

BIOBLOCKED®

- Medical barriered gowns; These are health equipment manufactured for use in hospitals, operating rooms, healthcare institutions.
- Resistant to liquids with its barrier feature.
- Resistant to moisture and bacterial penetration.
- Puncture, tear and abrasion resistant.
- Free from toxic substances.
- Lint and dust free.
- Ultrasonic stitches prevent leakage from these areas.
- It is extra reinforced in the arms and front part of body.

Velcro Tape

Velcro tape prevents opening of the collar.

Four Laces

Four-laced belt system insures secure fit.

Extra Reinforced in Arm Hole

The reinforcement in the armhole prevents liquid infiltration and provides added protection.

Extra Reinforced on Front

Extra reinforcement on the front part and arms provides a barrier thus rendering the equipment more resistant by blocking infiltration of liquids.This provides extra security.

Sterile: SG 0240-S
Non-Sterile : SG 0240

BIOBLOCKED®

Surgical Gown - Reinforced

Product Code : SG 0240

Documents :

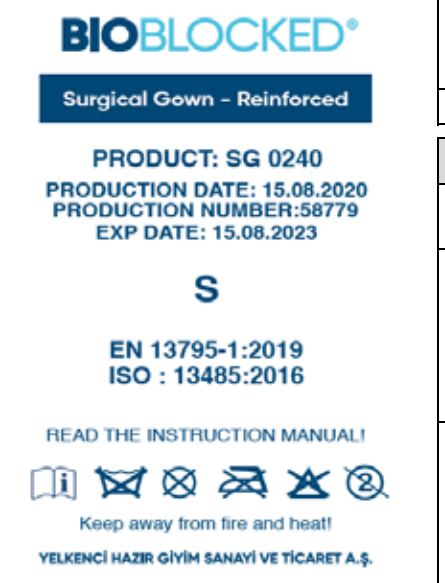
- **TECHNICAL SHEET**
- **ATTESTATION OF CONFORMİTY**
- **EU DECLARATION OF CONFORMITY**
- **FDA CERTIFICATE**
- **LAB REPORT**
- **TECHNICAL FILE**

Standards :

- **EN 13795 - 1 : 2019**

Preparation date: 14.06.2020

T.010.01	TECHNICAL SHEET
BRAND	BIOBLOCKED
PRODUCT	Surgical Gown - Reinforced (NON-STERILE)
PRODUCT CODE	SG 0240



PRODUCT INFORMATION	
Model Description	It is a disposable medical gown with arm and front body barriers, 4 straps at the waist, rib on the arm and and laces and hook and loop on back nape.
Fabric	40 gr SMS + 23 gr PE Film
Material	Number 120 white polyester yarn.
	7 cm long and 2 cm wide white hook and loop.
	Collar pipe is made of 30 gr spunbound material.
	Collar Lace: It will be 30 cm on both sides, Rib: The finished version should be 8 cm x 6.5 cm, there should be no rotation and the mixture is 98% Polyester + 2% Acr.

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)
	Strap and skirt cuts will be symmetrical and smooth.
	5 thread overlock will be used in all inerlace stitches.
	The sleeve hem ribs will be fitted with 5 thread overlock.
	While fastening the collar piping, 7 cm X 2 cm hook and loop fastening will be sewn together. The loose part of the hook and loop will be completed on the straight machine.
	Left and right shoulder seams will be sewn starting from the collar and the stitches will be attached and end at the cuff.
	A total of 4 straps will be sewn to the product, 2 from inside and 2 from outside. From the rear open snap, 1 piece 5 cm from the inside of the right and 1 piece from the left outside will be sewn. 1 belt will be sewn symmetrically from the inside, right inside from the armpit, right and left inside. All four straps will be sewn on the visible side of the hook and loop.
	The label will be attached to the left shoulder with an overlock stitch from the 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 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.
	30X40+5 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.

UNIVERSALCERT.COM

UNIVERSAL
CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate No: MDD-237

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

the products manufactured by

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ

at the following address

E5 Karayolu üzeri 5001 Sk. No:6 Selimpasa- Silivri - ISTANBUL / TURKEY

EN 13795-1:2019 Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns

Brand Name: BIOBLOCKED
Model: SG 0240
(Standard Performance) are tested according to the following initial type tests by the manufacturer
For the assessment of conformity, the following documents were also reviewed:
Laboratory test results for Microbial Penetration (wet/dry), Bioburden, Bursting and Tensile Strengths (wet/dry)

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the surgical gowns manufactured and designed for use to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; performance level and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 25/08/2020 and valid until 24/08/2021 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

ISTANBUL –25/08/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

EU DECLARATION OF CONFORMITY

MANUFACTURER

YELKENCİ HAZIR GİYİMSANAYİ VE TİCARET ANONİM ŞİRKETİ
E5 Karayolu üzeri 5001 Sk. No:6 Selimpasa- Silivri - ISTANBUL / TURKEY

PRODUCT DESCRIPTION

Brand Name: BIOBLOCKED

Surgical Gown - Reinforced

Model: SG 0240

Surgical Gowns high standard performance to be used to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures, classified as Medical Device (Class I)

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

The Conformity is assessed especially with the following provisions:

- European Regulation (EU) 2017/745 and93/42/EEC Medical Devices Directive establishing technical requirements for medical devices, in effective wording
- Technical standard EN 13795-1:2019 Surgical Gown - Reinforced SMS.
- EN ISO 13688: 2013 standard Defines basic health and ergonomic requirements, general size definition, size change in washing and dry cleaning, markings, harmlessness, design and general features.
- Other relevant harmonized legislation and standards
- For the assessment of conformity, the following documents were also applied to:
- Results of laboratory tests for Microbial Penetration –DrybyNatıonalProtectıveTestıng LLC
- Results of laboratory tests for Microbial Penetration - Wet and Microbial Cleanliness, Bioburden by EkoteksLaboratuvarveGözetimHizmetleri A.Ş.
- Results of laboratory tests for Bursting and Tensile Strengths (wet/dry) by EkoteksLaboratuvarveGözetimHizmetleri A.Ş.
-

MARKING, LABELLING

Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the surgical gown is supplied. The information supplied with the product considering EN ISO 15223-1:2016 and EN 1041:2008+A1:2013.

MEASURES TO ENSURE CONFORMITY

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

Eren YELKENCİ
General Manager
25/05/2020

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Selimpaşa Mah. 5001 Sokak No:6/A Silivri / İST.
Tel : (0 212) 723 98 00 Fax : (0212) 723 98 15
Silivri Vergi Dairesi : 947 017 7579
Ticaret Sicil No : 457834

CE

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:	**GOWN, SURGICAL**
Product Code:	**FYA**
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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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: June 29, 2020

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

TÜRKAK
Test
TS EN ISO/IEC 17025
AB-0583-T

TEST REPORT
DENEY RAPORU

AB-0583-T
20028717-ing
08-20

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:	-
Name and identity of test item:	Blue non-woven gown. (BLUE GOWN, BLUE SMS GOWN WITH BARRIERS)
The date of receipt of test item:	14.08.2020
Re-submitted/re-confirmation date:	-
Date of test:	14.08.2020-24.08.2020
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

The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number [AB-0583-T] for ISO 17025:2017 as test laboratory.
The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.

Seal	***Date***	***Customer Representative***	***Head of Testing Laboratory***
TESTED BY EKOTEKS TEST EDİLMİŞTİR	24.08.2020	Özlem ULUS	Sevim A. RAZAK 24.08.2020

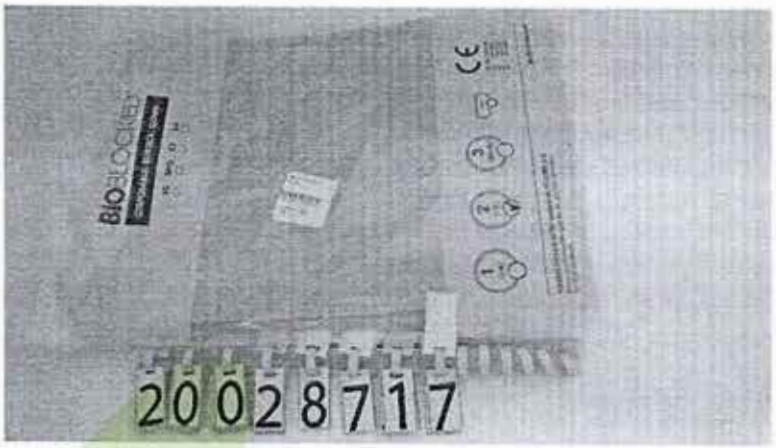
AB-0583-T
20028717-ing
08-20

REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
Dry-Bacterial Penetration	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)

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 after shaking well (250 rpm,5 min), inoculated on the suitable agar.The plates are incubated for 3 days at 30 ± 1 ° C for 72 hours, and 7 days at (20 to 25) °C for TSA and SDA plates respectively.
Total microoragnisms counts are calculated.

	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/g)	85 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

Gen.f136-2/03

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	0	R_{CUM4}	0
X_5	0	R_{CUM5}	0
Z	324		
T	324		

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	6	≥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

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	0
3	0
4	0
5	0
6 (Control)	0
Total	0
Logarithm	-

RESULT	
Result (cfu/g)	**Expected Value**
0	≤300 cfu/g

Gen.f136-2/03

AB-0583-T
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08-20

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	69.0 N	≥ 20N (Dry)
Warp	162.6 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	71.8 N	≥ 20N (Wet)
Warp	178.4 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 ;	228.2 kPa	≥ 40 kPa (Dry)
Height at Burst*	15.3 mm	

Gen.f136-2/03

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 ;	201.4 kPa	≥ 40 kPa (Wet)
Height at Burst*	13.0 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
	Main	**Barrier Part**	
Sample 1	26.5 cmSS	240.7 cmSS	≥ 20cmSS
Sample 2	27.0 cmSS	261.1 cmSS	
Sample 3	47.4 cmSS	255.0 cmSS	
Sample 4	36.7 cmSS	252.9 cmSS	
Sample 5	32.7 cmSS	258.1 cmSS	
Average	34.1 cmSS	253.6 cmSS	

TABLE OF CONTENTS - ABOUT THE MANUAL

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

On the pages of the Control Manual, "**YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET ANONİM ŞİRKETİ**" logo, "Technical File - Production Control Manual" phrase, Department Name, Document No (**TD-04**), Issue Date, Revision Date, Revision No, Page No and the information of the persons who Prepared (Title and Signature) Controlled (Title and Signature) and Approved (Title and Signature) are found. Page No; is given as "page no/total page no".

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

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

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET A.Ş.
Sefapaşa Mah. 5001 Sokak No:9/A Silivri / İST.
Tel : (0 212) 723 86 00 Fax : (0212) 723 86 15
Silivri Vergi Dairesi : 647 017 7579
Ticaret Sicil No : 457834

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.

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

2. REFERENCE STANDARD AND/OR DOCUMENTS

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

EN,ISO,IEC 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

3. Product Information

3.1 Product Description

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

3.2 Brand Name: BIOBLOCKED

3.3 Product Model No: SG 0240

Surgical Gown - Reinforced

3.5 Factory Manufacturing Control:

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

3.6 Materials and Intermediates Used

NO	MATERIAL USED	SPECIFICATION	PRODUCER INFORMATION
1	SMS FABRIC	35 gr/m2 SMS,10 gr/m2 PE FILM,14 gr/m2 SB ,4 gr/m2 ADHESIVE	Bayteks Tekstil
2	SEWING THREAD	Coast No 120 Threats	COATS
3	PACKING MATERIAL - BAG	PRINTED BAG	DEKA PLASTİK
4	PARCEL	KSSK QUALITY	MERCAN AMBALAJ
5	TAPE	Tape	AKT MENSUCAT SAN. TİC. LTD. ŞTİ.
6	HOOK AND PILE	White Hook and Pile	ANTEKS TEKSTİL SAN. TİC. LTD. ŞTİ.
7	RIB	Knitted Rib	ELSA FORM VATKA KAPİTONE VE TEKSTİL

3.7 Product Photos (Annex A)

3.8 Marking (Annex B)

3.9 Instructions for Use (Annex C)

3.10 Basic Health and Safety Requirements of the Product (Annex D)

3.11 Essential Health and Safety Requirements Fulfilled by the Product (Annex E)

3.12 Stitch Joining Section

All roof stitches are made with 5 thread overlock stitch. The back, belt and bias stitches are sewn with straight stitches.

3.13 Machinery and equipment used in the production of the product; Cutting table, Cutting motor, Overlock machine, Flat machine.

- Flat Machine
- Overlock Machine
- Cutting Engine
- Marker Table
- Modelroom Mold Drawing Machine

4. REQUIREMENTS

4.1 MANUFACTURING CONTROL

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

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

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

4.2 QUALITY PLAN

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

-Organizational structure of the manufacturer in terms of compliance and quality
-Document control
-Checking the component materials and the products it supplies
-Process control
-Conditions for the transportation and storage of the product,
-Requirements for inspection and testing of processes and products
-Methods to be applied in case of non-compliance

4.3 ORGANIZATION

4.3.1 Responsibility and Authority

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

- Starting a process to prevent the production of nonconforming product,
- Identification and recording of any quality problem in the product.

4.3.2 Management Representative

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

REFERENCE

Management Representative Appointment Letter

4.3.3 Internal audits

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

REFERENCE

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

4.3.4 Management Review

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

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Silivri Vergi Dairesi: 647 017 1579
Ticaret Sicil No: 457834

REFERENCE
MR Meeting Minutes

4.3.5 Subcontractor Services

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

4.4 Document Control

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

REFERENCE

Document Control Procedure

Record Control Procedure

5 CONTROL METHODS

5.1 Component Materials

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

Surgical Clothing and Drapes have been established for the required component materials used in production, and tolerances have been established and these are notified to the supplier in writing.

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

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

5.2 Product supplied by the customer

No component material in Surgical Clothing and Drapes supplied by the customer is used and in such a situation, the necessary conditions will be provided by our company.

5.3 Control of Operations

The quality plan includes the following issues.

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

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

c) Stitch control, stitch pitch frequency control, stitch type control, sealing tape control used in the seams, if any

d) Dimension control

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

f) Label user manual and packaging control

5.4 Transport, Storage and Distribution

It covers the procedures to ensure hygiene rules during transportation and storage of Surgical Clothing and Drapes.

REFERENCE
Transport, Storage, Maintenance and Shipment instruction

6 INSPECTION AND TESTS

6.1 General

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

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

6.2 Input Component Material

Input component materials are examined and tested using the processes detailed in the input quality plans. If the quality plan of the supplier is also included in the quality plan of our company, the results of the tests carried out by the supplier can be used.
In order to prevent any deterioration in storage, necessary inspections of the materials continue.

7 NONCONOFRMITY STATUS

7.1General

Our company has documented and ensures its maintenance to prevent the use and application of the product that does not comply with the specified requirements, provided that it is reasonably applicable. This control is necessary for identification, evaluation and decomposition (where practical) and disposal of the nonconforming product. All the procedures to be performed have been documented and a system has been formed to inform the user if the shipment of the nonconforming product cannot be prevented.

Nonconformity may occur in the following stages;

a) In the component materials in the warehouse,
b) If the product is processed,
c) In the transportation, storage and distribution of the product.

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

REFERENCE
Nonconforming product control procedure

7.2 Nonconformity of component materials

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

a) Reprocessing of component materials
b) Adjusting the manufacturing control to separate nonconforming components
c) Rejection and elimination of nonconforming material

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REFERENCE
Nonconforming product control procedure

7.3 Nonconforming staus of the final, finished product (from the result of the examination of the processes carried out)

Nonconforming Surgical Clothing and Drapes are evaluated and necessary methods are followed to take corrective measures. Some measures consist of the following:

a) Reprocessing and acceptance of shipment of nonconforming product, if applicable,
b) If it is not feasible to be reprocessed, to be directed to alternative use,
c) Rejection of the product,

REFERENCE
Nonconforming product control procedure

Quality plan

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

In case the component material or Surgical Clothing and Drapes that are being studied do not meet the specification requirements, the corrective measures taken to ensure the product quality of the materials are recorded.

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

REFERENCE
Sample Label
Analysis Reports
Quality Records Control Procedure

9 Training

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

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

REFERENCE

Training records
Training plan

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Annex A

PRODUCT PHOTOS

Annex B

MARKING

YELKENCİ HAZIR GİYİM SANAYİ VE TİCARET AŞ

E5 Karayolu üzeri 5001 sk. No:6 Selimpasa- Silivri - ISTANBUL /TURKIYE

13.3. Information that should be on the label:

a) The manufacturer's name or commercial name and address must be included, for imported medical devices, the name or commercial name and address of the authorized representative and/or importer should also be included on the label or on the sales packaging or in the instruction manual,
b) Detailed information that defines the contents of the package and the medical device, and especially for the user,
c) "STERILE" phrase where necessary,
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 medical device is custom made, the words "custom made device",
h) If the medical 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.

Annex C

INSTRUCTIONS FOR USE

BIOBLOCKED®

Surgical Gown - Reinforced

PRODUCT: SG 0240

PRODUCTION DATE: 15.08.2020
EXP DATE: 15.08.2023

S

EN 13795-1:2019
ISO : 13485:2016

READ THE INSTRUCTION MANUAL!

Keep away from fire and heat!

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S-M L-XL 2XL-3XL

CE

TS EN 13795-1
ISO 9001:2015
ISO 13485:2016
ISO 14001:2015
ISO 22716:2007

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Selimpaşa Merkez Mh. 5001 Sk. No. 6/A Silivri İstanbul

BioBlocked.com

ENGLISH

PRODUCT FEATURES

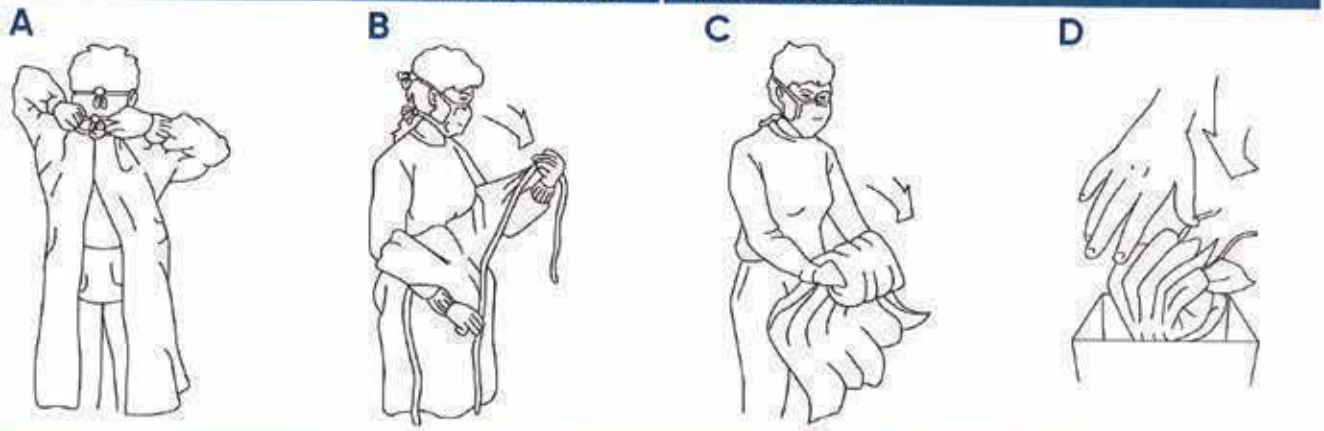
- SMS Fabric with PE Barrier
- Non-Sterile.
- Long sleeved gown with open back, under knee length.
- Barrier protection to prevent blood strikettrough and fluid contamination.

TÜRKÇE

ÜRÜN ÖZELLİKLERİ

- SMS, PE bariyerli
- Steril değildir.
- Uzun kollu, sırt bölgesi açık, diz altı önlük.
- Kan sıçraması ve sıvı kontaminasyonunu önlemek için bariyer koruması.

USAGE INSTRUCTIONS / KULLANIM TALİMATLARI



ENGLISH

INSTRUCTION FOR REMOVAL

A- It is held from the shoulders,
B- Contaminated outer face is turned inwards,
C- Fold by rolling,
D- When removed, only the clean side should appear.

TÜRKÇE

ÖNLÜK NASIL ÇIKARILIR ?

A- Omuz kısımlarından tutulur,
B- Kontamine dış yüz içe doğru çevrilir,
C- Yuvarlanarak katlanır,
D- Çıkarıldığında sadece temiz taraf görünmelidir.

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.

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.

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

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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 détaillance 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 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**

S-M 8 692753 520817
L-XL 8 692753 520824
2XL-3XL 8 692753 520831

Product: SG 0240
Exp. Date: 07/23

BIOBLOCKED®

SAFETY INSTRUCTION: All Surgical Clothing and Drapes should be checked for defects and faults that may cause negativity such as tears, holes, ripped dirt before use. If they are faulty and dirty, they should not be worn.

Caution! Playing with the bag is dangerous, it can cause choking. Please keep it away from children and babies.

STORAGE/EXPIRATION: It is recommended to be stored in carton or cardboard boxes at 15 -25°C away from sunlight. If stored under suitable conditions, it should be used within 3 years after the production date.

DISPOSAL AND RECYCLING: Non-contaminated products can be treated as general garbage or recycled. On the other hand, contaminated products should be treated as harmful wastes and disposed 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."

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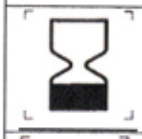
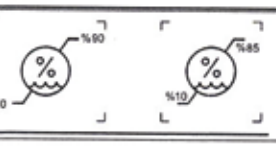
Disposable "Do not reuse!"

Meaning of Symbols in Product Packaging

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

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	See instructions for use	Indicates that the user should consult the 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.

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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.

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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:

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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:

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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.