CERTIFICATE

EC Certificate
Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-17-459

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

BİOTEX MEDİKAL TEKSTİL İTHALAT İHRACAT SANAYİ VE TİCARET ANONİM ŞİRKETİ

İslampaşa mahallesi 2 Nolu Şehitler Caddesi No: 41/G Merkez, Rize, Turkey

Products: Sterile Disposable Surgical Drapes, Gowns and Sets

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number:	M.5022.02
Date of first issue:	28 August 2017
Date of last issue:	05 March 2020
Revision Number:	01
Expiry Date:	27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions in accordance with MDD Annex V and found that the quality system meets the applicable requirements in MDD Annex V.

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

05 March 2020, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
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RİTAŞ
PAZARLAMA İÇ VE DIŞ TİC.AŞ.

TURKEY'S SECOND 500 INDUSTRIAL ENTERPRISES 2010
Gaziantep

Yeni Otogar Yolu 2. Km, P.O.B. 66 Şehitkamil - Gaziantep / TÜRKİYE
Tel.: +90 342 3295000 - Fax: +90 342 3290971 - www.ritas.com.tr - ritas@ritas.com.tr

RIBOND PP SPUNBOND NONWOVEN FABRIC
TECHNICAL DATA SHEET

(MEDICAL APPLICATIONS)

Product	Spunbond Nonwoven (SMS Type)
Content	100 % Polypropylene
Denier	< 2,5
Maximum Width	3200 mm
Number of Beams	3 - 4
Pattern Design	Sesame / Oval Design
Grammage Variance Tolerance	+/- 5%
Color	Any color upon customer request
Inner Core Diameter	3 or 6 inches
Packing	In transparent PE bags
Application	Disposable medical textile products production, medical film production

Weight	Tensile Strength N/5cm		Elongation (%)		Water Column (mm WC)
	MD	CD	MD	CD	
25 GSM	50<	27<	55<	55<	230<
30 GSM	63<	35<	55<	55<	280<
35 GSM	75<	38<	55<	55<	330<
40 GSM	83<	47<	60<	60<	380<
43 GSM	95<	50<	60<	60<	400<
45 GSM	97<	53<	60<	60<	430<
50 GSM	105<	63<	60<	60<	440<
60 GSM	110<	65<	60<	60<	460<

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

TEST REPORT
DENEY RAPORU

20024484-ing
07-20

Customer name:	UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.
Address:	Yukarı Dudullu Mahallesi, KEYAP E2 No:84, 34775 Dudullu Organize Sanayi Bölgesi/Ümraniye/İstanbul
Buyer name:	BİOTEX MEDİKALTEKSTİL İTHALAT İHRACAT SAN. VE TİC. A.Ş.
Contact Person:	SUAT KAÇMAZ
Order No:	-
Article No:	-
Name and identity of test item:	Blue surgical gown
The date of receipt of test item:	15.07.2020
Re-submitted/re-confirmation date:	-
Date of test:	15.07.2020-24.07.2020
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

Seal — TESTED BY EKOTEKS TEST EDİLMİŞTİR

Date
24.07.2020

Customer Representative
Servin YURTSEVEN

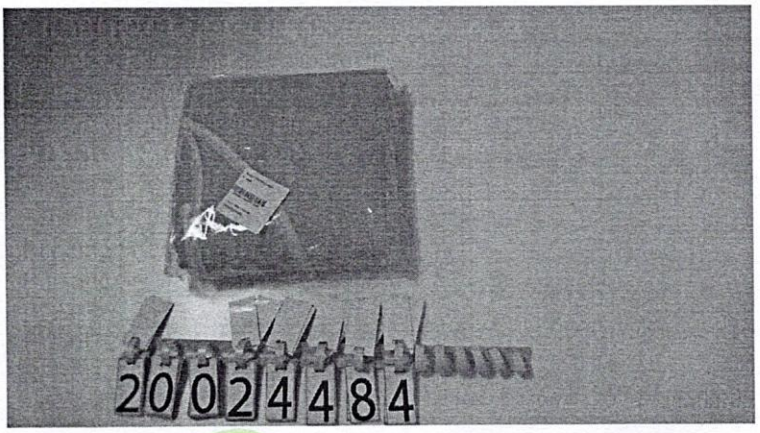
Head of Testing Laboratory
Sevim A. RAZAK

Gen.f136-2/03

20024484-ing
07-20

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	
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)		

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.



20024484-ing
07-20

TEST RESULTS

Surgical clothing and drapes - Requirements and test methods – Part 1: Surgical drapes and gowns EN 13795-1 :2019

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: EN ISO 11737-1:2018 /TS 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)	190 cfu/100 cm^2	≤300 cfu/100 cm^2

***cfu= Colony forming unit.**

20024484-ing
07-20

TEST RESULTS

WET-BACTERIAL PENETRATION

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):	$2x10^5$ 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	128	R_{CUM4}	0,22
X_5	156	R_{CUM5}	0,43
Z	294		
T	578		

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	5,3	≥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.*

Gen.f136-2/03

20024484-ing
07-20

TEST RESULTS

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	1
2	2
3	5
4	7
5	1
6 (Control)	0
Total	17
Logarithm	1,23

EVALUATION	
Result	**Class (*)**
1 < log kob ≤ 2	2

** EN 14126: 2003 Protective Clothing - Performance Properties and Test Methods of Protective Clothing Against Infectious Agents are evaluated according to Table-4.*

Sınıf	**Penetrasyon (log kob)**
3	*≤ 1*
2	1 < log kob ≤ 2
1	2 < log kob ≤ 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**
17 cfu/g	≤300 cfu/g

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20024484-ing
07-20

TEST RESULTS

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

Instron 5969 (Load: 5 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 width and length direction of four samples
Performed in the conditioned room (20±2°C-65%±4).

Dry ;

	RESULT	REQUIREMENT
Width	49.9 N	≥ 20N (Dry)
Length	80.2 N	≥ 20N (Dry)

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

Instron 5969 (Load: 5 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 width and length direction of four samples
Performed in the conditioned room (20±2°C-65%±4).

Wet ;

	RESULT	REQUIREMENT
Width	53.9 N	≥ 20N (Wet)
Length	76.9 N	≥ 20N (Wet)

Gen.f136-2/03

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Dry ;	124.5 kPa	≥ 40 kPa (Dry)
Height at Burst*	12.4 mm	

20024484-ing
07-20

TEST RESULTS

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Wet ;	103.3 kPa	≥ 40 kPa (Wet)
Height at Burst*	12.3 mm	

Gen.f136-2/03

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UNIVERSAL
CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate No: MDD-203

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

BİOTEX MEDİKAL TEKSTİL İTHALAT İHRACAT SAN. VE TİC. AŞ.

at the following address

İslampaşa Mah. 2 nolu Şehitler Cad. No:41/G Merkez RIZE / TURKEY

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

Brand Name: BIOTEX
Model: RCÖ-MUMS-125
(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 29/07/2020 and valid until 28/07/2021 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 –29/07/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

This certificate will be in the absence of any changes in standard and legal terms, and with the surveillance audits to be concuted annually following the surveillance audits, updating the publicationdate without changing the certificate number.

EU DECLARATION OF CONFORMITY

MANUFACTURER

BİOTEX MEDİKAL TEKSTİL İTHALAT İHRACAT SAN. VE TİC. A.Ş
İslampaşa Mah. 2 nolu Şehitler Cad. No:41/G Merkez RIZE / TURKEY

PRODUCT DESCRIPTION

Brand Name: BIOTEX
Model: RCÖ-MUMS-125

Surgical Gowns with 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 and 93/42/EEC Medical Devices Directive establishing technical requirements for medical devices, in effective wording
- Technical standard EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
- 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 - Wet and Microbial Cleanliness, Bioburden by Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş.
- Results of laboratory tests for Bursting and Tensile Strengths (wet/dry) by Ekoteks Laboratuvar ve Gözetim Hizmetleri 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

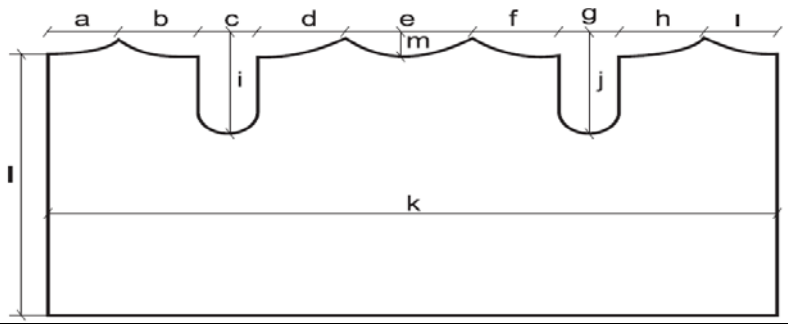
The Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

General Manager
29/07/2020

CE

Scheda Tecnica Camici Chirurgici

Riferimento Conformità
Certificato CE nr. 1984-MDD-17-459
Emesso da : KIWA Turkey
Organismo Notificato nr.: 1984
Descrizione del Prodotto
Art. RCO-40MUMS-125 - Camice Chirurgico Standard NON Sterile monouso Dispositivo Medicale – Tipo I Colore Blu – TNT da 30 gr/m2 ±5 Allacciatura sul dietro sovrapponibile, maniche lunghe con polsini in maglia elasticizzata, drappeggiabile, semplice da indossare, vestibilità ampia e comoda grazie alla cura nella definizione delle taglie. Materiale anallergico e Latex free. Idrorepellente, Traspirante, Antistatico, Cinture in vita per chiusura interna –esterna, girocollo rinforzato; Resistenza elevata allo strappo in trazione longitudinale e trasversale, Confezione del corpo in un unico pezzo, senza cuciture verticali e/o orizzontali , Cuciture termosaldate ad ultrasuoni Piegatura tale da esporre la parte interna del camice e da consentire agevolmente la vestizione, materiale resistente al fuoco.



Dimensioni

	a	b	c	d	e	f	g	h	ı	i	j	k	l	m
S	12	15	12	15	25	12	12	12	15	23	23	130	125	7
M	13	16	12	16	25	13	12	13	16	25	25	136	125	8
L	14	17	12	17	25	14	12	14	17	27	27	142	120	9
XL	15	18	12	18	25	15	12	15	18	29	29	148	120	10
XXL	16	19	12	19	25	16	12	16	19	31	31	154	120	11

Norme di Riferimento e di conformità
ISO 9001
EN 13485
EN ISO 11737
EN ISO 10993-1:2009
EN ISO 14791:2012
EN 1041:2008
EN 15223-1:2013
EN 13795:2013

Sterilizzazione
Non applicabile

Utilizzo
USO : L'abbigliamento protettivo monouso per uso medico (NON Sterile) è destinato a fornire barriera e protezione al personale medico a contatto con sangue, fluidi corporei, secrezioni e particelle sospese nell'aria di pazienti potenzialmente infettivi. **Limitazioni:** In caso di allergia ai tessuti non tessuti o problemi cardiaci, consultare il medico prima dell'uso.

Avvertenze:

1. Solo per uso singolo. Non usarlo più volte.
2. Prima dell'uso, leggere le istruzioni e vestirsi correttamente.
3. Prima dell'uso, controllare la confezione, il numero del modello del prodotto, la data di produzione, la data di scadenza e utilizzarlo entro la data di scadenza.
4. Prima di indossarlo verificare se vi sono danneggiamenti e/o difetti .
5. Se si osservano danneggiamenti e/o difetti non indossare per evitare la possibile esposizione ai rischi.
6. Questo prodotto può essere utilizzato in un ambiente chirurgico sterile.
7. In caso di incidenti gravi verificatisi in relazione al dispositivo. Si prega di riferire al produttore e all'autorità competente di la tua zona.

Come indossare:

(1) Indossare prima le braccia;
(2) Avvolgerlo intorno al corpo;
(3) Chiuderlo mediante i lacci .

Come togliere il camice:

(1) Slacciare i lacci
(2) Sfilare il camice iniziando dalle braccia rovesciando le maniche
(3) Sfilare tutto il resto del camice arrotolando il lato esterno del camice verso l'interno
(4) Gettarlo negli appositi contenitori di smaltimento

Conservazione e Durata

- Conservare in luogo asciutto ed al riparo dal sole
- Temperatura min -10°C / Max +40°C
- Se la confezione è danneggiata o nel dubbio sia danneggiata non utilizzare il camice per evitare l'esposizione al rischio.
- Durata: 3 anni dalla data di produzione (vedi confezione) salvo diversa indicazione presente sulla confezione.