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Manufacturer

ZERKAYA TEKSTİL MEDİKAL GIDA İNŞAAT İTH. İHR. SAN. VE TİC. LTD. ŞTİ.

Adress: Alaybey mah. Güzelce Sk. No:16/2 Şahinbey/Gaziantep - TURKEY
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Medical Devices Regulation (EU) 2017/745

We declare that the product described below meets the requirements of the relevant provisions of the regulation as a result of the Medical Devices Regulation (EU) 2017/745
This statement will lose its validity if the product whose information is specified below is changed.

Product description	: DISPOSABLE BED SHEET
Brand	: ZERKAYA
Risk class	: Class I, non-measuring, non-sterile (in accordance with the rules set out in Medical Devices Regulation (EU) 2017/745 Annex VIII)
Model number	: ZRK-06
Lab	: Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş. Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar/ İstanbul - Turkey
Test number	: 20019164
Applicable EC directives:	Medical Devices Regulation (EU) 2017/745
Applicable standarts	: EN 13795-1:2019, EN 29073-3:1996, EN ISO 13938-1:1999, EN ISO 11737-1:2018, EN 22610:2006, EN ISO 22615:2005
Publication Date	: 23.06.2020



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Mersis No: 0998119399700001



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Doc number: 20062304



Lab: EKOTEKS LABORATUVAR VE GÖZETİM HİZMETLERİ A.Ş.**Address: Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar / İstanbul - Turkey****Test no: 20019164-ING**

Customer name:	ZERKAYA TEKSTİL GİYİM GIDA İTH. İHR. SAN. TİC. LTD. ŞTİ.
Address:	ALAYBEY MAH. GÜZELCE SOK. NO:16/2 ŞAHİNBEY/GAZİANTEP
Buyer name:	-
Contact Person:	AYÇA AKSOY
Order no:	-
Article no:	-
Name and identity of test item:	Non-woven drape.
The date of receipt of test item:	15.06.2020
Re-submitted/re confirmation date:	-
Date of test:	15.06.2020-23.06.2020
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:	3

The Turkish Accreditation Agency (TURKAK) is signatory of 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 result the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.

**Seal
EKOTEKS****Date
23.06.2020****Customer Representative
Özlem ULUS****Head of Testing Laboratory
Sevim A. RAZAK**


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20019164- ING



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	REQUIREMENTS
Microbial cleanliness (cfu/g)	85 cfu/g	≤ 300 cfu/g Type I and Type II mask

EKOTEKS
TEXTILE LABORATORY

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TEST RESULTS

Test Method: BS EN 22610: 2006 (Surgical drapes, garments and fresh air clothes used was 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 ($3N \pm 0.02$). 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 preated by inverting the sample.

Sample amount:	5 pieces 25x25cm2
Carrier Material:	30 μ m thin, 25x25cm2 Polyurethane Film
Coating Material:	25x25 cm2 HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / ml):	1-4 104 kob /ml
Incubation Conditions:	(36 \pm 1) °C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		Penetration Rate	
X ₁	0	Rcum1	0
X ₂	0	Rcum2	0.002
X ₃	0	Rcum3	0.01
X ₄	14	Rcum4	0.04
X ₅	18	Rcum5	0,09
Z	287		
T		319	

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: $X_1 + X_2 + X_3 + X_4 + X_5 + Z$

Rcum1 = X_1/T

Rcum2 = $(X_2 + X_1) / T$

Rcum3 = $(X_3 + X_2 + X_1)/T$

Rcum4 = $(X_4 + X_3 + X_2 + X_1)/T$

Rcum5 = $(X_5 + X_4 + X_3 + X_2 + X_1)/T$

BARRIER INDEX (IB)		
	Result	Expected value(*)
Ib	5,85	$\geq 2,8$

Ib = 6 - (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)

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

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