

UNICERT®



QUALITY MANAGEMENT SYSTEM CERTIFICATE

Universal GmbH

This certificate is granted to the organization,

**ZEYNI MEDIKAL TEKSTIL INS.
SAN. VE TIC. LTD. STI.**

Yunus Emre Mah. 12.Yildirim Sok. No 17 Yildirim-BURSA/TURKEY

by review of IA2-5076 numbered report for the scope

**MANUFACTURE AND SALES OF DISPOSABLE SURGICAL STERILE GOWNS,
DRAPES AND CUSTOM PACKS, NON-STERILE MEDICAL TEXTILE PRODUCTS**

to certify that a management system in accordance with
standard's clauses is established and being implemented

DIN EN ISO 9001:2015

Certificate No : QMS 0520 006861

Original Certification Date : 22.04.2020

Issue / Revised Date : 22.04.2020

Expiry Date : 21.04.2021

Certification Period : 3 years (1st year)



Deutsche
Akkreditierungsstelle
D-ZM-16058-01-00

Universal GmbH

The authenticity of this certificate can be confirmed online or by e-mail to the Head Office via:

UNIVERSAL GmbH • Wilfried Diekmann Str., 20b, 44536 Lünen Germany • T : +49 (0) 231 9931 9960 • info@uni-cert.de • www.uni-cert.de

UNICERT®



MEDICAL QUALITY MANAGEMENT SYSTEM CERTIFICATE

Universal GmbH

This certificate is granted to the organization,

ZEYNI MEDIKAL TEKSTIL INS. SAN. VE TIC. LTD. STI.

Yunus Emre Mah. 12.Yildirim Sok. No 17 Yildirim-BURSA/TURKEY

by review of IA2-5076 numbered report for the scope

**MANUFACTURE AND SALES OF DISPOSABLE SURGICAL STERILE GOWNS,
DRAPES AND CUSTOM PACKS, NON-STERILE MEDICAL TEXTILE PRODUCTS**

to certify that a management system in accordance with
standard's clauses is established and being implemented

DIN EN ISO 13485:2016

Certificate No : MDMS 0520 006861

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Issue / Revised Date : 22.04.2020

Expiry Date : 21.04.2021

Certification Period : 3 years (1st year)



Universal GmbH

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Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Production Quality Assurance No. 09 0816 QS/NB

The quality system of manufacturer

Zeyni Medikal Tekstil Ins. San. Ve Tic. Ltd. Sti.

Yunus Emre Mah. 12.Yıldırım Sok. No 17 Yıldırım –BURSA, Turkey

has been certified as meeting the requirements of

Directive 93/42/EEC
on medical devices, Annex V

for the following product category(ies):

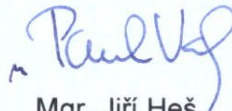
Sterile Disposable Surgical Gowns and Drapes and Drape Sets

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. The Notified Body has audited this system with limitation to those aspects of manufacture concerned with securing and maintaining sterile conditions. This part of quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance.

Valid from: 2020-09-08
Valid until: 2021-11-24
First Issued: 2009-11-26
Revision: g



Date: 2020-09-08


Mgr. Jiří Heš
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 09 0816 QS/NB

issued for manufacturer:

Zeyni Medikal Tekstil Ins. San. Ve Tic. Ltd. Sti.
Yunus Emre Mah. 12.Yıldırım Sok. No 17 Yıldırım –BURSA, Turkey

Drape set types	Code number
Percutaneous drape set	901-002-S
T.U.R drape set	901-003-S
Ear-nose-throat drape set	902-001-S
Vertebra surgery drape set	903-001-S
Arthroscopy drape set	904-001-S
Extremity drape set	904-002-S
Hip surgery drape set	904-003-S
Rinoplasty set	905-001-S
Vertebra set	906-001-S
I.V.F. Drape set	907-001-S
E.T set	907-002-S
Abdominal drape set	908-001-S
Hand surgery set	904-004-S
Chemotherapy drape set	909-001-S

Name: Gowns
Trade name(s): -
Model(s): see table below
Class: Is
GMDN: 35778

Gown Types	
Standard Surgery Gowns	100-001-S
Protected Surgery Gowns	200-001-S

Date: 2020-09-08
Revision: g



Mgr. Jiří Heš
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 09 0816 QS/NB
issued for manufacturer:

Zeyni Medikal Tekstil Ins. San. Ve Tic. Ltd. Sti.
Yunus Emre Mah. 12.Yıldırım Sok. No 17 Yıldırım –BURSA, Turkey


Product(s):

Name: Drape sets
Trade name(s): -
Model(s): see table below
Class: Is
GMDN: 47783

Drape set types	Code number
General surgery drape set	101-001-S
Laparoscopy drape set	201-001-S
Minor surgery drape set	102-001-S
Dressing surgery drape set	103-001-S
Spinal surgery drape set	301-001-S
Craniotomy surgery drape set	401-001-S
Shunt surgery drape set	401-002-S
Valve Replacement surgery drape set	501-001-S
Cardiovascular Thoracic drape set	202-001-S
Anjyo drape set	601-001-S
By-pass drape set	602-001-S
Ophthalmic drape 1	701-001-S
Ophthalmic drape 2	701-002-S
Caesarean drape set	801-001-S
O.P.U surgery drape set	802-001-S
Delivery drape set	802-002-S
Dental drape set	803-001-S
Biopsy drape set	804-001-S
Cystoscopy drape set	901-001-S

Date: 2020-09-08
Revision: g




Mgr. Jiří Heš
Representative of the Notified Body No. 1023



EC Declaration of Conformity

issued in accordance with EC directive 93/42/EEC relating to Medical Devices

Manufacturer: Zeyni Medikal Tekstil Ins. San. Ve Tic. Ltd. Sti.
Address: Yunus Emre Mah. 12.Yıldırım Sok. No 17 Yıldırım-BURSA/ TURKEY
Commercial name: Zeyni Medikal
Product name: Sterile Disposable Surgical Gowns and Drapes
Applied directives: The Directive 93/42/EEC on medical devices, conformity assessment according to Annex VII + Annex V (as a Class I sterile device)
Applied harmonized Standards: ISO 11135:2014, ISO 14644-3 :2019, 13795-1:2019, ISO 14971:2012, ISO 15223-1:2016, ISO 10993-1:2018, ISO 10993-7:2008, ISO 14937:2009
Notified Body: ITC (Institute for Testing and Certification, a.s) Trida Tomase Bati 299, Louky, 763 02 Zlin /Czech Republic
Identification Number: 1023
EC Certificate: 09 0816 QS/NB rev. g
EC Certificate Validity: 24.11.2021

The company **Zeyni Medikal Tekstil Ins. San. Ve Tic. Ltd. Sti.** herewith declares that the above-mentioned product meets all applicable provisions of the Directive 93/42/EEC. The product is safe under prescribed and reasonably foreseeable conditions of storage and use.

The company has implemented measures assuring that all products of the above mentioned type are safe and fulfil essential requirements of the 93/42/EEC Directive.

The company has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions. The company undertakes to notify the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of patient's health as well as on technical or medical reason leading to systematic recall of the product by manufacturer.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid in relation to the modified product.

Date of issue: 10th, April, 2020

Numan CAVDAR, President
On Behalf of Company

ZEYNI MEDİKAL
TEKSTİL İNŞAAT SANAYİ VE TİC. LTD. ŞTİ.
Yunus Emre Mah. 12. Yıldırım Sk. No:17
Yıldırım / BURSA / T.C. Sic. No:102917
Yıldırım / BURSA / T.C. Sic. No:102917
Mersis No:0950 1411 4000 0001

TCF.001-AnnexIV(Rev 00,Rev Date 10.04.2020)

ZEYNI MEDİKAL TEKSTİL İNŞ. SANAYİ VE TİCARET LTD.ŞTİ.
Yunus Emre Mah. 12. Yıldırım Sk. No: 17 Yıldırım - BURSA / TÜRKİYE
Tel.: 0224. 369 32 32 Faks: 0224. 369 32 36 e-mail : info@zeynimedical.com.tr
www.zeynimedical.com.tr





T.C.
TÜRK PATENT ve MARKA KURUMU

MARKA TESCİL BELGESİ

Marka No : 2019 44841 - Ticaret - Hizmet

TURCARE

Marka Sahibi : ZEYİN MEDİKAL TEKSTİL İNŞAAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ
TÜRKİYE CUMHURİYETİ
Yunus Emre Mah. 12.Yıldırım Sk. NO: 17 Yıldırım Bursa

Emtiası : 10 , 35
İlişiktir.



İşbu Marka 05/05/2019 tarihinden itibaren ON YIL süreyle
18/11/2019 tarihinde tescil edilmiştir.

Prof. Dr. Habip ASAN
Türk Patent ve Marka
Kurumu Başkanı

