

**Zeyni Medikal Tekstill Ins. San. Ve Tic. Ltd. Sti**

**Yunus Emre Mah. 12. Yildirim Sok. N° 17 Yildirim -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 set 1	701-001-S
Ophthalmic drape set 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
Biopsie drape set	804-001-S
Cystoscopy drape set	901-001-S

GENERAL DIRECTOR:

*Baki Canar*  
07.06.22

STAMP & SIGNATURE

**ZEYNI MEDİKA**  
**TEKS.İNŞ. SAN VE TİC. LTD. ŞTİ.**  
Yunusemre Mh. 12. Yildirim Sk. No: 17 Yildirim -BURSA  
Yildirim V.D.: 998 141 1400 Ticaret Sic. No: 270902  
Mersis No: 09981411400000000000

**Zeyni Medikal Tekstill Ins. San. Ve Tic. Ltd. Sti**

**Yunus Emre Mah. 12. Yildirim Sok. N° 17 Yildirim -BURSA, Turkey**

<b>Drape set types</b>	<b>Code number</b>
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

**Product(s):**

**Name:** GOWNS

**Trade name(s):** -

**Model(s):** See table below

**Class:** Is

**GMDN:** 35778

<b>Gown Types</b>	<b>Code number</b>
Standard Surgery Gowns	100-001-S
Protected Surgery Gowns	200-001-S

GENERAL DIRECTOR:

Baki Canavar

07.06.22

STAMP & SIGNATURE

**ZEYNI MEDİKAL**  
**TEKS.İNŞ. SAN.VE TİC. LTD.ŞTİ.**  
Yunus Emre Mah. 12. Yildirim Sok. No: 17 Yildirim/BURSA  
Yildirim V.K. 999041 Yasa: 102917  
Tic. Sic. No: 268144400000000000



**ZEYNI  
MEDICAL**

**For medical devices, regulated in accordance with EC Directive 93/42/EEC**

**EC Declaration of Conformity**

**11042020-UB**

Manufacturer : ZEYNI MEDİKAL TEKSTİL İNŞAAT SAN. VE TİC. LTD. İST.

Address : Yunus Emre Mah. 12. Yildirim Sok. No: 17 Yildirim-Bursa / TURKEY

Trade name : Zeyni Medical

Product Name : STERILE AND DISPOSABLE SURGICAL SUPPORTS, COVERS AND COVER SETS

STERILE AND DISPOSABLE SURGICAL LINERS, DRAWER AND LID SETS

(The list of products is given in appendix-1.)

Classification : Class 1-Sterile (with sterile function)

Conformity assessment according to Annex VII and the annexes of the applied directives  
(Medical Device Directive 93/42/EEC; Class 1-as sterile device)

Applied harmonized standards: ISO 11135:2014, ISO 14644-3 2019, 13795 1 2019 ISO 14971  
2012, 150 15223-1:2016, ISO 10993-7:2008, ISO 14937 2009

Notified body: ITC (Institute for testing and Certification, a s) Trida T Bati 299,76421 Zlin-Loky/  
Czech Republic

Notified body number: CE 1023

EC certificate: 090816QS/NB

Validity of the CE certificate: 24.11.2022

GENERAL DIRECTOR:

*Baki Cnacer*

*07.06.22*

STAMP & SIGNATURE

**ZEYNI MEDİKAL**  
**TEKS.İNŞ. SAN.VE TİC.LTD.ŞTİ.**  
Yunus Emre Mah. 12. Yildirim Sok. No: 17 Yildirim/BURSA  
Yildirim V.D.: 998 144 1400 (Tic Sic No: 107917)  
Mersis No: 9981400000000000000

**ZEYNI**  
**MEDICAL**

Zeyni Medikal Tekstil İnş San. and Tic. Ltd. Şti hereby declares that the above mentioned products are in compliance with all applicable provisions of Directive 93/42/EEC. The product is safe under foreseeable and reasonably foreseeable conditions of storage and use.

The company has put in place measures to ensure that all products of the type mentioned above are safe and meet the essential requirements of Directive 93/42/EEC

The company has put in place a systematic procedure to review experience gained with the devices in the post-production phase and to apply appropriate means for any necessary corrective action and keeps this systematic procedure up to date. The company undertakes to report to the competent authority any malfunction or alteration in the properties, performance or inadequacy of the product's instructions for use that could lead to the death of the patient or serious damage to the patient's health, as well as the or medical reasons that led to the systematic recall of the product by the manufacturer.

If the device is modified without the consent of the undersigned, this statement becomes invalid with respect to the modified product.

Regulated in accordance with EC Directive 93/42/EEC concerning medical devices

EC DECLARATION OF CONFORMITY

11042020-UB

GENERAL DIRECTOR:

*Baki Canavar*  
*07.06.22*

STAMP & SIGNATURE

**ZEYNI MEDİKAL**  
TEKS.İNŞ. SAN.VE TİC.LTD.ŞTİ.  
Yunusemre Mh. 12. Yıldırım Sk. No: 12 Yıldırım/BURSA  
Yıldırım V.D.: 999 441 400 Ticaret No: 102317  
Mersis No: 099904140000001