



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: 2020-06-23

Valid until: 2021-11-24

First Issued: 2009-11-26

Revision: f



Date: 2020-06-23

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



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Annex to EC Certificate No. 09 0816 QS/NB

issued for manufacturer:

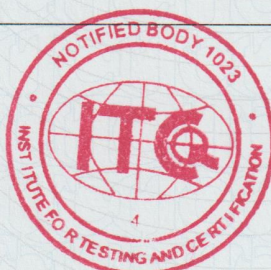
Zeyni Medikal Tekstil Ins. San. Ve Tic. Ltd. Sti.
Yunus Emre Mah. 12.Yıldırım Sok. No 17 Yıldırım –BURSA, Turkey

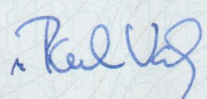
Product(s):

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




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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
Rhinoplasty 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

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Facility(ies):

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

Certificate History:

Revision	Date	Reference Number	Action
	2009-11-26	803600649	Certification
a	2011-05-20	343600834	Addition of new Drape Set types and the change of address of the company seat
b	2013-06-28	343601776	Change of address of the company seat
c	2014-11-24	343603069	Prolongation of the certificate validity
d	2016-11-22	803602550	Re-certification process
e	2020-03-03	833600132	Change of address of the company seat
f	2020-06-23	803602850	Change of company name
g	2020-09-08	803602857	Change of GMDN codes

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