

**ZENMED**TIBBİ CİHAZLAR VE SAĞLIK  
ÜRÜN. SAN. VE TİC. LTD. ŞTİ.

## EC DECLARATION OF CONFORMITY

**MANUFACTURER:** ZENMED TIBBİ CİHAZLAR VE SAĞLIK ÜRÜNLERİ SAN. VE TİC. LTD. ŞTİ.

**ADDRESS:** MAHMUTBEY MAHALLESİ 2567. SOKAK NO: 1/11, 21 BAĞCILAR – İSTANBUL / TURKEY

**PRODUCT:** PRODUCT LIST GIVEN ANNEX I

PRODUCT	GMDN CODE
SURGICAL DRAPES	47783
SURGICAL GOWNS	35778
SURGICAL SETS	33961

**CLASSIFICATION:** CLASS 1S, RULE 1, ANNEX IX OF MDD 93/42 EEC.

**CONFORMITY  
ASSESSMENT ROUTE:** ANNEX V

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC (2007/47/EC) FOR MEDICAL DEVICES, DO NOT CONTAIN HUMAN BLOOD AND DERIVATIVES, DO NOT CONTAIN ANIMAL TISSUE, DO NOT CONTAIN DRUG AND PHARMACEUTICAL COMPONENTS. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

THE PRODUCTS ARE "LATEX FREE"

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VE SAĞLIK ÜRÜNLERİ SAN. VE TİC. LTD.ŞTİ.  
Mahmutbey Mah. 2567.Şk. No:1 İş Yeri No:11,21  
Bağcılar / İSTANBUL / TÜRKİYE  
Tel: 0212 445 45 25 Tic.Sic.No: 794704  
Güneşli V.D.: 997 067 1942



# ZENMED

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DISPOSABLE STERILE  
REINFORCED SURGICAL  
GOWN S,

DISPOSABLE STERILE  
REINFORCED SURGICAL  
GOWN L,

DISPOSABLE STERILE  
REINFORCED SURGICAL  
GOWN XXL,

DISPOSABLE STERILE  
STANDARD SURGICAL GOWN  
M,

DISPOSABLE STERILE  
STANDARD SURGICAL GOWN  
XL,

DISPOSABLE STERILE  
REINFORCED SURGICAL GOWN  
M,

DISPOSABLE STERILE  
REINFORCED SURGICAL GOWN  
XL,

DISPOSABLE STERILE STANDARD  
SURGICAL GOWN S,

DISPOSABLE STERILE STANDARD  
SURGICAL GOWN L,

DISPOSABLE STERILE STANDARD  
SURGICAL GOWN XXL,

DISPOSABLE STERILE GENERAL SURGERY SET, DISPOSABLE  
STERILE UNIVERSAL SET, BIRTH SET  
CESAREAN SET

#### APPLICATION STANDARDS:

EN ISO 13485: 2012	MDD 93/42/AT	EN ISO 14971: 2012
EN ISO 15223-1: 2016	EN 1041: 2014	EN 62366-1: 2015
EN ISO 10993-1: 2011	EN ISO 10993- 5: 2010	EN ISO 10993-10: 2014
EN ISO 11607-1: 2010	EN ISO 11607- 2: 2006	MEDDEV 2.12/1 rev.8
MEDDEV 2.12/2 rev.2	MEDDEV 2.7/1 rev.4	TS ISO 13795+A1
TS EN ISO 22612: 2016	EN ISO 14644- 1: 2015	EN ISO 11135: 2014
EN ISO 14644-2: 2015	EN ISO 14644- 3: 2005	EN ISO 14644-4: 2001
EN ISO 14644-5: 2004	EN ISO 14644- 6: 2007	EN ISO 14644-7: 2004

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ÜRÜN. SAN. VE TİC. LTD. ŞTİ.

**PRODUCTS:** SURGICAL GOWNS, SURGICAL DRAPES, SURGICAL SETS.

**NOTIFIED BODY** : KIWA BELGELENDİRME HİZMETLERİ

**NOTIFIED BODY ADDRESS** : İTOSB 9. Cad. No: 15 Tepeören - TUZLA -  
İSTANBUL

www.kiwa.com.tr

**NOTIFIED BODY NUMBER** : 1984

**START OF CE-MARK** : 20.04.2018

**VALIDITY OF CE-MARK** : 27.05.2024

**REVISION NUMBER** : 02

**NUMBER OF CERTIFICATE(S)** : M.5071.03

**PLACE, DATE OF ISSUE** : İSTANBUL / 10.09.2021

**SIGNATURE:** : M. ZEKİ KÜÇÜKKAYA  
General Manager

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