

**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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Mahmutbey Mah. 2567.Sk. No:1 İş Yeri No:11,21
Bağcılar / İSTANBUL / TÜRKİYE
Tel: 0212 445 45 25 Tic.Sic.No: 794704
Güneşli Y.D.: 997 067 1942

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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

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SIGNATURE:: M. ZEKİ KÜÇÜKKAYA
General Manager

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