



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
STERILE SURGICAL DRAPES	47783
STERILE SURGICAL GOWNS	35778
STERILE 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"

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

PRODUCTS:

STERILE SURGICAL GOWNS, SURGICAL DRAPES, STERILE 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

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REVISION NUMBER

: 02

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SIGNATURE:: M. ZEKİ KÜÇÜKKAYA
General Manager

**ZENMED TIBBİ CİHAZLAR
VE SAĞLIK ÜRÜNLERİ SAN. VE TİC. LTD.ŞTİ.**
Mahmutbey Mah. 2567.Sk. No:1 İş Yeri No:11,21
Bağcılar / İSTANBUL / TÜRKİYE
Tel: 0212 445 45 25 Tjic.Sic.No: 794704
Güneşli YD.: 897 067 1942

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