



**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**

: 27.05.2024

**REVISION NUMBER**

: 02

**NUMBER OF CERTIFICATE(S)**

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

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