DECLARATION OF CONFORMITY

MANUFACTURER: BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. A.Ş

Organize Sanayi Bölgesi 19 Nolu Cad. No:9 MERKEZ / KİLİS
Tel: 0342 337 30 30
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PRODUCTS : **Sterile Gowns, Drapes and Sets**

NOTIFIED BODY : **KİWA BELGELENDİRME HİZMETLERİ A.Ş. ITOSB 9.CADDE NO:15 TEPEÖREN TUZLA - İSTANBUL - TÜRKİYE**

ID NO : **1984**

CERTIFICATION NO : **M 5035.3**

CLASSIFICATION : Class IS Rule 1 MDD 93/42/ECC Annex IX

EXECUTED ANNEX : MDD 93/42/ECC (For all versions).

ANNEXV : Conformity Assessment Route.

APPLIED STANDARDS : EN ISO 13485:2016, ISO 14971:2012, EN ISO 11135:2014, EN556-1:2001/AC:2006, EN ISO 15223-1:2012, EN ISO 11737-1:2006, EN ISO 11737-2:2009, EN ISO 14644, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-7:2008/AC:2009, EN 13795:2011+A1:2013, EN 1041:2008+A1:2013, EN ISO 11607-1:2009+A1:2014, EN ISO 11607-2:2006+A1:2014, EN ISO 19011:2011, BS EN 62366-1:2015

APPLICATION : The directive for our product is the Council Directive 93/42 / EECfor all versions of medical devices.The Manufacturer of the product, Bayteks Teknik Tekstil San. And Tic. A.Ş, is responsible for the requirements of this council directive. Our products are not medical devices that contains human blood derivatives, animal products, animal skin, tissues, or blood derivatives or phthalates.

STERILE PRODUCTS

#	PRODUCT NAME	Size	REF. CODE	GMDN CODE
1	Disposable Surgical Pack (Head&Neck Surgical Drape Pack)	St	30100005041	47783
2	Disposable Surgical Drape (Cable Pouch)	17x240 cm	30100005032	47783

The products listed in the list above and their contents are classified Class 1 Sterile products. These products ,their content, and their accessories do not take part in any other class.We herewith declare that the above mentioned products conforms general requirements of the Council Directive 93/42/EEC for all versions of Medical Device Directive .

Applied Directives

Medical Device Directive MDD 93/42/EEC (incl. 2007/47/EC) ANNEX V ALL VERSIONS.

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REV.NO. : 3
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