

**UYGUNLUK BEYANI / DECLARATION of CONFORMITY**

**İMALATÇI / MANUFACTURER :**

GENJECT SAĞLIK ÜRÜNLERİ VE KİMYA SAN. VE TİC. A.Ş.

İMALATÇI ADRESİ / MANUFACTURER ADDRESS:

SARAY MAH. FATİH SULTAN MEHMET BULVARI NO: 407/B KAZAN/ANKARA – TÜRKİYE  
İLETİŞİM BİLGİLERİ : TEL : +90 312 815 44 84 FAX : +90 312 815 44 94 [www.genject.com](http://www.genject.com)

**ÜRÜN ADI ve KODU / PRODUCT NAME and CODE :**

KANGAZLI ŞİRINGASI İĞNELİ (İLYYUM HEPARİN İÇERMEKTEDİR) / BLOOD GAS SYRINGE WITH NEEDLE  
ÜRETİM ve SON KULLANMA TARİHİ / MANUFACTURING and EXPIRY DATE

Label

**PARTI NO/ LOT NUMBER :**

Label

**UYGULANAN STANDARTLAR / APPLIED STANDARTS**

EN ISO 13485:2012, TS EN ISO 10993-1/AC:2010, TS EN 1041+A1:2014, TS EN ISO 10993-10:2011, TS EN ISO 10993-11:2010, TS EN ISO 10993-5:2010, TS EN ISO 10993-4:2010, TS EN ISO 10993-1:2010, EN ISO 14971:2012, EN 556-1:2001, TS EN ISO 7886-1:1998, TS 3521-2 EN 1707:2001, TS EN ISO 15223-1:2012, EN ISO 11137-2:2012, EN ISO 14155:2012, TS EN ISO 11607-1:2010, TS EN ISO 11607-2:2010, EN ISO 11737-1:2006, TS EN ISO 11737-1/AC, TS EN ISO 14644-3:2013, TS EN ISO 7886-2:2006, TS EN ISO 14644-1:2001, TS EN ISO 14644-2:2006, TS EN ISO 14644-3:2006, EN ISO 62366:2008, TS 11605 EN ISO 14644-1

**UYGULANAN DİREKTİFLER / APPLIED DIRECTIVES**

**MEDICAL DEVICES DIRECTIVE 93/42/ EEC, CLASS I/II A Kural 6 EK II**

WE HERE WITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL

DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL

SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

**FİRMA SORUMLUSU / RESPONCE OF COMPANY**

**BÜLENT BATTAL YER-TARİH / PLACE-DATE : ANKARA 26.10.2015**

**EC Certificate No/ CE Sertifiكا No : M.2015.106.5477**

ÜDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic.Ltd. Şti.

GMDN CODES: 58095

NOTIFIED BODY : 2292

ADRES

Mutlukent Mah. 2073 Sokak No: 10 Çankaya-ANKARA

ÇANKAYA/ ANKARA/TÜRKİYE

**YETKİLİ İMZA / LEGALLY BINDING SIGNATURE :**

**BÜLENT BATTAL**

Yayın Tarihi: 11.11.2011

Rev. Tarihi : 26.10.2015 Rev No: 03

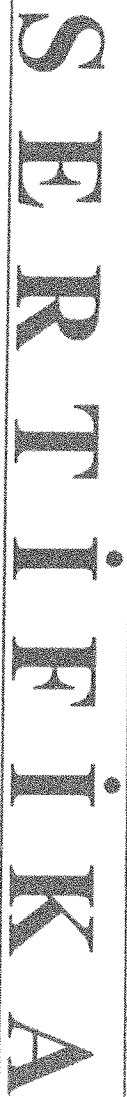
**Genject** İMALATÇI ADRESİ  
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**Genject Sağlık Ürünleri ve Kimya San. Ve Tic. A.Ş.**

Saray Mah. Fatih Sultan Mehmet Bulvarı No: 407/B Kazan-Ankara

Tel: 0312 815 44 84 • Faks: 0312 815 44 94



# Tam Kalite Güvence Sistemi

Gençer Sağlık Ürünleri ve Kimya San. ve Tic. A.Ş.

: Saray Mah. Fatih Sultan Mehmet Bulvarı No: 407/B Kazan  
ANKARA/ TÜRKİYE

: MDD 93/42/AT Tıbbi Cihazlar Yönetmeliği - Ek II  
(Madde 4 Haric)

**Tek Kullanmak İçin Steril Ürünler**

- Kan Gazi Şingası - İğnelli
- Hipodermik Şırınga - İğnelli - Contalı / Contasız (2 ml-2,5 ml-5ml-10 ml-20 ml-50 ml)
- Beslenme Enjektörü - İğnesiz (50 ml)

14.2015.106.5477

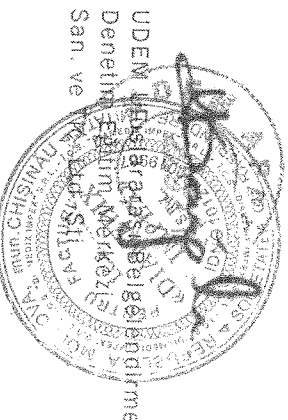
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18.09.2015

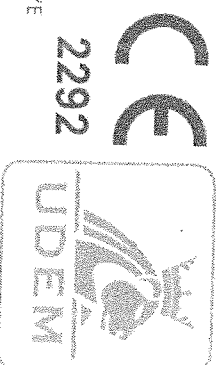
26.10.2015

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25/10/2020

[illegible]

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# C E R T I F I C A T E

## Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II

Company Name : Gençetçi Sağlık Ürünleri ve Kimya San. ve Tic. A.Ş

Company Address : Saray Mah. Fatih Sultan Mehmet Bulvarı No: 407/B Kat: 3  
ANKARA / TÜRKİYE

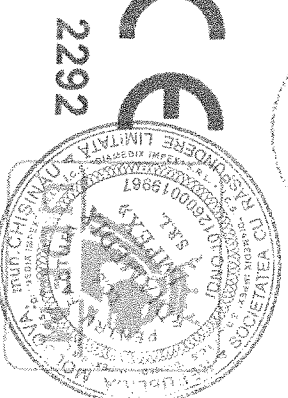
Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex II  
(Excluding Section 4)

Product : Disposable Class IIa Sterile Products

- Blood Gas Syringe With Needle
- Hypodermic Syringe With Needle - Sealed / Nonsealed  
(2 ml-2.5 ml-5ml-10 ml-20 ml-50 ml)
- Nutrition Injector Without Needle ( 50 ml)

Certificate Number : M.2015.106.5477  
Report Number : MD.3003.IB  
Initial Assessment Date : 18.09.2015  
Registration Date : 26.10.2015  
Reissue Date/No : -  
Expiry Date : 25.10.2020

UDEM International Certification  
Auditing Training Centre Industry  
and Trade Co. Ltd.



UDEM hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has explained and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the aforementioned directive. According to Annex II, section 4 or EC design examination certificate is required for placing the Class II devices on the market. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the declaration of EC Declaration of Conformity. The above mentioned company must notify of changes related with the approved product to UDEM. If UDEM will not review the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The currency of the certificate can be checked through [www.udemid.com.tr](http://www.udemid.com.tr).

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