

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

ÜRÜN ADI ve KODU / PRODUCT NAME and CODE :

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

Label

PARTİ 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 14644-8:2013, 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 IIA 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 / RESPONSE OF COMPANY

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

EC Certificate No/ CE Sertifika No : M.2015.106.5477

UDEM 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

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

Saray Mah. Fatih Sultan Mehmet Bulvarı
No: 407/B Kazan-ANKARA
Tel: 0 (312) 815 44 84 - Faks: 0 (312) 815 44 94
Kazan Mah. Müdülül Sokak 234 045 4428

Yayın Tarihi: 11.11.2011

Rev. Tarihi : 26.10.2015 Rev No: 03



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



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 : Genject Sağlık Ürünleri ve Kimya San. ve Tic. A.Ş.

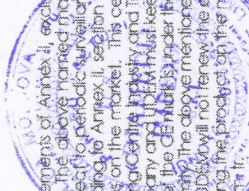
Company Address : Saray Mah. Fatih Sultan Mehmet Bulvarı No: 407/B Kazan
ANKARA / TURKEY

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 /Nonssealed
(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

U. Sarıhan
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 established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 of the EC design-examination certificate is required for placing the Class IIa 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. UDEM is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. UDEM will not renew 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.udemtd.com.tr.

CE
2292



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