

UYGUNLUK BEYANI / DECLARATION of CONFORMITY

IMALATÇI / MANUFACTURER :

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

IMALATÇI ADRESİ / MANUFACTURER ADRESS:

SARAY MAH. FATİH SULTAN MEHMET BULVARI NO: 407/B KAZAN/ANKARA – TÜRKİYE

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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

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 14644-8:2013,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 ISO14644-1

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

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