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SERTİFİKA

Berika Teknoloji Medikal İmalat İth. İhr. Tic. Ltd. Şti.

Alakova Mahallesi Karaman Cad. No:812 Meram KONYA / TÜRKİYE

ISO 13485:2016

Kapsam: Steril tek kullanımlık hipodermik iğne, steril tek kullanımlık şırıngalar ve kan gazı şırıngası üretimi ve satışı, Serum seti-İnfüzyon setler üretimi ve satışı

AKSSERT Denetim ve Belgelendirme Limited Şirketi bu belge ile adı geçen kuruluşun yukarıdaki standardın şartlarına uygun bir yönetim sistemine sahip olduğunu belgeler. Sistem etkin bir şekilde sürdürüldükçe ve gözetim denetimleri zamanında yapıldığı müddetçe bu belge tescil tarihinden itibaren 3 yıl boyunca geçerlidir. Belgenin geçerliliği www.akssert.com, www.jas-anz.org/register. internet sayfalarından kontrol edilebilir. Bu belgenin mülkiyet hakkı AKSSERT Denetim ve Belgelendirme Limited Şirketi' ne aittir ve istenildiğinde iade edilmelidir.

Referans alınan standart ISO 13485:2016'dir

Belge 04.08.2022-19.10.2022 tarihleri arasında yürürlükte değildir.

AKSSERT Denetim ve Belgelendirme Ltd. Şti.

akssert JAS-ANZ

SertifikaNumarası: 85237
Tescil Tarihi: 05.08.2016
Bir Önceki Belgelendirme Döngüsü
Geçerlilik Tarihi : 04.08.2022
Yeniden Belgelendirme Denetim Tarihi : 05.07.2022

Yeniden Basım Tarihi: 19.10.2022
Revizyon Tarihi /No: -
GeçerlilikTarihi: 04.08.2025

Adres: Mutlukent Mah. 1920.Cadde No:28 Çankaya / ANKARA - TÜRKİYE
Tel: +90 312 284 99 44(pbx)
E-posta: info@akssert.com **Web:** www.akssert.com

CERTIFICATE

Berika Teknoloji Medikal İmalat İth. İhr. Tic. Ltd. Şti.

Alakova Mahallesi Karaman Cad. No:812 Meram KONYA / TURKEY

ISO 13485:2016

Scope: Production and sale of sterile disposable hypodermic needle, sterile disposable syringes and blood gas syringe, Serum set-Infusion sets

Hereby, AKSSERT Audit and Certification Ltd. Co., certificates that the above stated company gave the appropriate management system according to the requirements of the above standard. This certificate valid for 3 years since the decision date as long as the system is effectively maintaned and surveillance audits are carried out. The validity of certificate can be checked through www.akssert.com, www.jas-anz.org/register. The Certificate is property of AKSSERT Audit and Certification Ltd. Co. and shall be returned if requested.

The reference standard is ISO 13485:2016

The certificate is not in force between 04.08.2022-19.10.2022

AKSSERT Audit and Certification Ltd. Co.

Certificate Number : 85237
Registration Date : 05.08.2016
Previous Certification Cycle Expiry Date: 04.08.2022
Recertification Audit Date: 05.07.2022

Reissue Date : 19.10.2022
Revision Date/No : -
Expiry Date : 04.08.2025

Address: Mutlukent Mahallesi 1920. Cadde No:28 Çankaya/ANKARA - TÜRKİYE
Phone: +90 312 284 99 44(pbx)
E-mail: info@akssert.com **Web:** www.akssert.com

CERTIFICATE

Production Quality Assurance

Medical Devices Directive 93/42/EEC Annex V

Company Name : Berika Teknoloji Medikal İmalat İth. İhr. Tic. Ltd. Şti.

Company Address : Alakova Mah. Karaman Cad. No:812 Meram KONYA / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex V

Product : Sterile Single Use Syringe - Class IIa
- 1 Ml. 3 Pieces Steril With Needle/Without Needle
- 2 Ml. 3 Pieces Steril With Needle/Without Needle
- 3 Ml. 3 Pieces Steril With Needle/Without Needle
- 5 Ml. 3 Pieces Steril With Needle/Without Needle
- 10 Ml. 3 Pieces Steril With Needle/Without Needle
- 20 Ml. 3 Pieces Steril With Needle/Without Needle
- 50Ml. 3 Pieces Steril With Needle/Without Needle

Sterile Single Use Hypodermic Needles - Class IIa
- Pink 18G 1 ½ 1.20x38mm
- Yellow 20G 1 ½ 0,90x38mm
- Green 21G 1 ½ 0,80x38mm
- Black 22G 1 ¼ 0,70x32mm
- Blue 23G 1 ¼ 0,60x32mm
- Blue 23G 1 0,60x25mm
- Orange 25G 1 0,50x25mm
- Brown 26G ½ 0,45x13mm
- Grey 27G 1 ½ 0,40x38mm
- Grey 27G 2 ½ 0,40x50mm

Disposible Sterile Blood Gas Syringe With Needle - Class IIa

GMDN : 47017, 59230, 58095

Certificate Number : M.2016.106.6915
Report Number : MD.3159.IB
Initial Assessment Date : 16.07.2016
Registration Date : 05.08.2016
Recertification Assessment Date : 03.10.2019
Reissue Date / No : 24.02.2020/01
Revision Date /No : -
Expiry Date : 27.05.2024

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

UDEM hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev,ce is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. 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 completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com. tr.

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