EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2020.106.13928-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Tabib Farma İlaç Tıbbi Cihazlar Medikal Ortopedi Gıda Tarım Bitki Yağları Üretim İnş. Malz. San. Tic. Ltd. Şti.
Company Address	: Sanayi Mah. 3327 Sk. Gülpetek Sanayi Sitesi S Ada 3. Blok No:3 ISPARTA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Sterile Alcasis Bone Cement with Genta Antibiotics 41g Powder, 20 ml Liquid - Class III
GMDN	: 35217

This certificate has been designed due to Ministry of Health's 68869993-511.14-E221647 numbered scientific opinion on 30.09.2020, scope 93/42/AT Annex I Article 7.4

Certificate Number	: M.2020.106.13928
Report Number	: MD.3595.IB
Initial Assessment Date	: 04.07.2019
Registration Date	: 05.10.2020
Revision Date /No	: -
Expiry Date	: 27.05.2024

UDEM APPROVED 2292

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

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive 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 an EC design- examination certificate is required for placing the Class III devices on the market. 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 device 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 returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years [illegible] of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the [illegible] Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved [illegible] to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

Digitally signed by Perminov Andrei
Date: 2023.03.16 10:35:37 EET
Reason: MoldSign Signature
Location: Moldova

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

EC DESIGN EXAMINATION CERTIFICATE

93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2020.106.13928 the validity of the certificate M.2020.106.13928-1 will also end.

Company Name	: Tabib Farma İlaç Tıbbi Cihazlar Medikal Ortopedi Gıda Tarım Bitki Yağları Üretim İnş. Malz. San. Tic. Ltd. Şti.
Company Address	: Sanayi Mah. 3327 Sk. Gülpetek Sanayi Sitesi S Ada 3. Blok No:3 ISPARTA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Section 4)
Product	: Sterile Alcasis Bone Cement with Genta Antibiotics 41g Powder, 20 ml Liquid - Class III
GMDN	: 35217

This certificate has been designed due to Ministry of Health's 68869993-511.14-E221647 numbered scientific opinion on 30.09.2020, scope 93/42/AT Annex I Article 7.4

Certificate Number	: M.2020.106.13928-1
Report Number	: MD.3595.IB
Initial Assessment Date	: 04.07.2019
Registration Date	: 05.10.2020
Revision Date /No	: -
Expiry Date	: 27.05.2024

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

The EC desing examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, section 4 of the 93/42/EEC Directive 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 aforementioned directive. 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.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

THE REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY

Certificate No: 103113

Date of Issue : 22 October 2020

CERTIFICATE OF FREE SALE

To whom it may concern,

It is hereby certified that the products detailed in the attached schedule, which are manufactured by "TABİB FARMA İLAÇ TIBBİ CİHAZLAR MEDİKAL ORTOPEDİ GIDA TARIM BİT. YAĞ. ÜR. İNŞ. MAL. SAN. VE TİC. LTD.ŞTİ." (*Sanayi Mh. Gülpetek Sanayi Sitesi S Ada 3. Blok 3327 Sk. No:3 MERKEZ ISPARTA*), have been affixed with the CE mark in accordance with Medical Device Directives of the European Union (EU) and are freely sold in Turkey.

This certificate is issued to be given to the relevant competent authorities of "Germany" and is valid for 36 months from the date of issue.

The products listed in the attached schedule are registered from the date of issuance of this certificate and information about the current status of these products is accessible through https://utsuygulama.saglik.gov.tr/UTS/vatandas#/vatTibbiCihazListele.

Yours sincerely,

Asım HOCAOĞLU, Ph.D.
Head of Medical Devices
Registration and Coordination Department

Address: Sögütözü Mahallesi, 2176. Sokak No:5 06520 Çankaya/ANKARA
Phone: +90 312 218 30 00 Fax: +90 312 218 34 60 https://www.titck.gov.tr

Date of Issue : 22 October 2020

PRODUCT SCHEDULE

#	Barcode	Brand	Label Name	Reference No / Version / Model	GMDN Code
1	8681889057150	ALCASIS™	Bone Cement With Antibiyotic 41gr	291453/41G	35217

End of product schedule.

Asım HOCAOĞLU, Ph.D.
Head of Medical Devices
Registration and Coordination Department