



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

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

M.2017.106.8915-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name : Feel Tech Co., Ltd.

Company Address : 3,4 Floor, Standard Factory 2-dong, 511-1, 15, Jayumuyeok2-gil,  
Gunsan-si, Jeollabuk-do, Korea

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

Product : Synthetic, Monofilament suture, Non-coated, Violet Sterile single use  
polydioxanone suture with needle - Class III

GMDN : 16584

Certificate Number : M.2017.106.8915

Report Number : MD.3427.K.IB

Initial Assessment Date : 26.07.2017

Registration Date : 18.10.2017

Revision Date /No : -

Expiry Date : 17.10.2022

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

  
2292



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 an EC design-examination certificate is required for placing the Class III devices on the market. 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 currency of the certificate can be checked through [www.udem.com.tr](http://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](mailto:info@udemltd.com.tr) [www.udem.com.tr](http://www.udem.com.tr)