



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

## Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : İnci Dental Tıbbi Malz. San. ve Tic. Ltd. Şti.

Company Address : Defterdar Mah. Otakçılar Cad. E Blok Sit. No:74/4 Eyüpsultan  
ISTANBUL / TURKEY

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

Product : Non-Sterile Endodontic Rotary File - Class IIa

GMDN : 40529

Product Types are attached.

Certificate Number : M.2019.106.12436

Report Number : MD.3141.IB

Initial Assessment Date : 07.03.2019

Registration Date : 23.08.2019

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 II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied 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 II devices on the market. UDEM's responsibility for class I devices covered by the EC certificate 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 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 validity 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](http://www.udem.com.tr).



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This document containing 3 (three) pages is the Annex of the Certificate with the number M.2019.106.12436 and with the registration date of 23.08.2019 issued for "İnci Dental Tıbbi Malz. San. ve Tic. Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

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