



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 III 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.



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