EC CERTIFICATE

Production Quality Assurance for Medical Devices Directive 93/42/EEC Annex V

Company Name	: Fsm Dental Medikal Mak. San. Tic. San. Tic. Ltd. Şti.
Company Address	: Demetlale Mahallesi 406. Cadde No:12/E Demetevler Yenimahalle ANKARA / TURKEY
Related Directives and Annex	: MDD 93/42/EEC Medical Devices Directive - Annex V
Product	: Non-Sterile Acrylic Artifical Teeth - Class IIa Non-Sterile Composite Artifical Teeth - Class IIa Non-Sterile CAD CAM Acrylic Composite and Temporary Block -Class IIa
GMDN	: 38643, 31783

Certificate Number	: M.2018.106.10405
Report Number	: MD.3611.IB
Initial Assessment Date	: 18.05.2018
Registration Date	: 26.09.2018
Revision Date /No	: -
Expiry Date	: 25.09.2023

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 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.

CE 2292

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