



C E R T I F I C A T E

EC Design-Examination Certificate

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

With the expire of the certificate M.2020.106.13296 the validity of the certificate M.2020.106.13296-1 will also end.

Company Name : Burgeon Biyoteknoloji ve San. Tic. A.Ş.

Company Address : Saray Mah. 1500 Cad. No:30C Kahramankazan ANKARA / TURKEY

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

Product : NOVUMA Collagen Stimulating Calcium Hydroxyapatite Sterile Dermal Filling Material (1,5 cc) - Class III

GMDN : 33310

Certificate Number : M.2020.106.13296-1

Report Number : MD.4010.IB

Initial Assessment Date : 13.12.2019

Registration Date : 11.02.2020

Revision Date /No : 19.02.2020/01

Expiry Date : 27.05.2024


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

The EC design 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 applied 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 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.

Address: Mutfukent 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

