EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2020.106.13970-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Burgeon Biyoteknoloji ve San. Tic. A.Ş.
Company Address	: Saray Mah. 1500 Cad. No:30 C Kahramankazan ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Sterile Crosslinked Hyaluronic Acid (23mg/L) Intradermal Filler Material with Lidocaine (%0,3) - Class III
Models	: YS.Corintha, YS. Tuscan, YS. Iona, YS.Dora
GMDN	: 47887

This certificate has been designed due to Ministry of Health's 68869993-511.14-E.229716 numbered scientific opinion on 11.10.2020, scope 93/42/AT Annex I Article 7.4

Certificate Number	: M.2020.106.13970
Report Number	: MD.4010.IB
Initial Assessment Date	: 14.02.2020
Registration Date	: 30.10.2020
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 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. UDEM's responsibility for class I devices covered by the EC sertificate 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 returnedupon 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 thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

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