CERTIFICATE

Full Quality Assurance System

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

Company Name	: Notch Implant GMBH
Company Address	: Zum Schnüffel 6, 58540 Meinerzhagen GERMANY
Related Directives and Annex	: MDD 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Sterile Dental Implant and Closing Screw - Class IIb Non-Sterile Dental Abutment - Class IIb Non-sterile Gingiva and Healing Screw - Class IIb
GMDN	: 55848, 55847, 42354, 44879, 44880, 42352

Product Types are attached.

Certificate Number	: M.2018.106.10556
Report Number	: MD.3564.IB
Initial Assessment Date	: 12.01.2018
Registration Date	: 15.10.2018
Revision Date / No	: 04.02.2019/01
Expiry Date	: 14.10.2023

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 dev,ce 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

CE 2292

Addrres: Mutlukent 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