



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 : Norm Tıbbi Ürünler İth. İhr. San. ve Tic. Ltd. Şti.

Company Address : İvedik O.S.B. 1468. Cad. No:193 Yenimahalle ANKARA / TURKEY

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

Product : - Sterile Kyphoplasty Kit (Balloon Catheter (10 mm, 15 mm, 20mm), Balloon Expander, Bone Marrow Needle, Cannula, Cement Filler, Guide Wire, Bone Drill) - Class IIa
- Sterile Vertebroplasty Kit (Bone Marrow Needle, Cannula, Cement Filler, Guide Wire, Bone Drill) - Class IIa

GMDN : 47129

Certificate Number : M.2020.106.13734
Report Number : UD.1319.IB
Initial Assessment Date : 21.02.2020
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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 II 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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