



EC CERTIFICATE

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II

Company Name : Biosys Biyomedikal Mühendislik San. ve Tic. Ltd. Şti.

Company Address : Bilkent ATGB Cyberpark Cyberplaza A Blk 3. Kat 4a A303 Çankaya
ANKARA / TURKEY

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

Product : Intensive Care Ventilator - Class IIb

GMDN : 47244

Certificate Number : M.2017.106.8613

Report Number : MD.3416.IB

Initial Assessment Date : 12.05.2017

Registration Date : 05.07.2017

Revision Date /No : -

Expiry Date : 04.07.2022

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

CE
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UDEM hereby declares that the requirements of Annex II, excluding section 4 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 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. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd. 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.udemltd.com.tr.

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