



E C C E R T I F I C A T E

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

Company Name : İnspiramed Medikal Sanayi ve Ticaret A.Ş.

Company Address : Serbest Bölge 8. Cad. No:29 38070 Melikgazi KAYSERİ / TÜRKİYE

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

Product : Class IIb - Non-Sterile Product
- Haemodialysis Machine Disinfectant
- Haemodialysis Acidic and Basic Concentrates
- Haemodialysis Sodium Bicarbonate Cartridge
- Haemodialysis Sodium Bicarbonate Bag

GMDN : 35849, 47631

Certificate Number : M.2013.106.2211
Report Number : UD.1665.YB
Initial Assessment Date : 13.07.2013
Registration Date : 25.07.2013
Recertification Assessment Date : 11.05.2018
Reissue Date : 31.08.2018/01
Revision Date /No : -
Expiry Date : 30.08.2023


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 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 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 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.udem.com.tr.

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