



# EKEVYL 0653

## EC – CERTIFICATE

Certificate No.: **2008V623E**

Validity Date: **11/02/2008**

Expiry Date: **10/02/2013**

### PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE (Annex V of the Ministerial Decision KYA DY7/2480/94 – MDD 93/42/EEC)

We hereby certify that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality assurance system conforms with the relevant provisions of the aforementioned legislation.

Reference of the evaluation report: **V 623**

Manufacturer: Name: **TEMAK S.A.**

Address: **254, TATOIOU AVEN., 136 77 ACHARNAI GREECE**

Device concerned: Name of generic group: **WATER TREATMENT SYSTEM FOR THE PRODUCTION AND DILLUTION OF HEAMODIALYSIS SOLUTIONS.**

Name of types: **SERIES TEMAKMED**

Identification of the approved quality system: **KYA DY7/2480/94, ANNEX V.**

Site: **ACHARNAI, ATTIKI GREECE.**

The President of the Board

**K. Kouvaris**

The Managing Director

**G. Pappous**

*The CE 0653 Marking can be used on the products listed above.*

*This certificate is valid for the above mentioned period, provided that surveillance audits will prove the conformance of the quality system.*



**EKEVYL S.A.**

NOTIFIED BODY

Notified by European Commission

under number: 0653

**RESEARCH CENTER FOR BIOMATERIALS S.A.**