

## EC Type-Examination Certificate

DGM – 604

This is to certify that the defined representative samples of the products of:

**Eltec Co., Ltd.**  
**Shirakawa No. 6, Bldg. 2-18-5, Nishiki**  
**Naka-ku, Nagoya, Japan**

have been approved in conformity with the requirements of  
**Annex III and Annex I**  
of Council Directive 93/42/EEC concerning medical devices as transposed into Danish law.

The scope of the approval is:

**Blood warmers in class IIb**

DGM must be informed about any significant change made to the approved product. Changes to the approved product must receive further approval from DS Certificering A/S wherever the changes may affect conformity with the Essential Requirements or with the conditions prescribed for the use of the product. The EC Type-Examination certificate is issued pursuant to the DS Certificering A/S rules for the certification of medical devices in order to affix the CE mark.



**Bent Buus**  
Authorized person

Valid from:	2008-07-02
Valid until:	2013-07-02
Initial date of issue:	2008-07-02
Reference:	art3a0605v51f252

**DS Certificering A/S**

*Notified Body, Identification No. 0543*  
Kollegievej 6, DK-2920 Charlottenlund, Denmark

The following products in class IIb are covered by the certificate:

**Blood warmer ANIMEC AM-413**  
**Blood warmer ANIMEC AM-2S-4A**  
**Blood warmer ANIMEC AM-2S-5A**

The authorized EC representative:

**P.N. Gerolymatos S.A.**  
35 Mihalakopoulou Str.  
GR-115 28 Athens  
Greece

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Certificate

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