

EC Type-Examination Certificate

DGM – 604

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

Elltec 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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