

# EC Certificate

**DGM – 558**

This is to certify that the quality system of

## **Elltec Co., Ltd.**

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

has been approved in conformity with the requirements of

### **Annex V, section 3.2 - Production quality assurance**

of Council Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law.

The scope of the certification is:

### **Manufacture and final inspection of blood warmers in class IIb and nutrition warmers in class IIa**

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of DS Certificering A/S. The EC certificate is issued pursuant to the DS Certificering A/S rules for the certification of medical devices and entitles the certificate holder to affix the CE mark.



**Bent Buus**  
Authorized person

Valid from:	2008-07-02
Valid until:	2011-12-22
Initial date of issue:	2006-12-22
Reference:	aur5a0807v40f252.

### **DS Certificering A/S**

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

The following product family in class IIb is covered by the certificate and  
by EC Type Examination certificate DGM – 604:

**Blood warmers**

The following product families in class IIa are covered by the certificate:

**Nutrition warmers**

The authorized EC representative:

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

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