

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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