

EC-Certificate

(full quality assurance system)

according to annex II, section 3 of
Medical Devices Directive 93/42/EEC

It is herewith confirmed by

**EUROCAT Institute for
Certification and Testing**

Quarat[®] Center * Wittichstrasse 2
D-64295 Darmstadt * Germany
Identification No. 0535,
in its function as Notified Body,

that the manufacturer

**Hydrosun Medizintechnik GmbH
Mauchener Str. 14**

79379 Müllheim, Germany

concerning the medical device

**infrared-whole-body hyperthermia-
device**

(products/variants specified in enclosure)
fulfills the requirements according
to Annex II, section 3,
Medical Devices Directive 93/42/EEC.

The manufacturer has established a quality
assurance system for the design, production
and final inspection of specified devices.

The enclosure is part of this certificate and
contains 1 page.

Based on the periodical surveillance the
certificate is valid until 12 November 2012.

Report No.: BQM07297RT06

Certificate No.: CQ073172-II

CE 0535

Accreditation granted by
Zentralstelle der Länder
für Sicherheitstechnik

ZLS

ZLS-ZQ-302/06

Darmstadt, 13 November 2007


Certification Body



Enclosure of EC-Certificate

(full quality assurance system)

according to annex II, section 3, Medical Devices Directive 93/42/EEC

Certificate No.: CQ0x73172-II

Medical devices of the manufacturer:

Hydrosun Medizintechnik GmbH

Mauchener Str. 14

79379 Müllheim, Germany

Name of product	Variant	Item	UMDNS	Class
infrared-whole-body hyperthermia-device	A	HT 3000	17-570	IIb

CE 0535

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Darmstadt, 13 November 2007



Certification Body