

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



BIOSUN[®]

Biosun GmbH

Steinstraße 5

35641 Schwalbach, Germany

concerning the medical device

BIOSUN Earcandle

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.

Date of initial registration: 18 June 2004.

Based on the periodical surveillance the
certificate is valid until 14 February 2012.

Certificate No.: CQ070461-II



[Signature]
INSTITUTE
FOR CERTIFICATION
AND TESTING
EUROCAT[®]
CERTIFICATION & TESTING

Certification Body

CE 0535

Accreditation granted by
Zentralstelle der Länder
für Sicherheitstechnik

ZLS

ZLS-ZQ-236/04

Darmstadt, 15 February 2007