



EC-Certificate

(full quality assurance system)
according to annex II (excluding section 4) of
Medical Devices Directive 93/42/EEC

It is herewith confirmed by

**EUROCAT Institute for
Certification and Testing**

Quarat® Center * Wittichstraße 2
64295 Darmstadt * Germany

in its function as Notified Body (0535), that the manufacturer:



**Lützelwiesen 5
35428 Langgöns, Germany**

concerning the medical devices

**EEG-monitors and systems
for evoked potentials**

(products/variants specified in appendix)

fulfils the requirements according to Annex II (excluding
section 4) Medical Devices Directive 93/42/EEC. The
manufacturer has established a quality assurance system for
the design, production and final inspection of specified
devices.

For the placing on the market of class III products an Annex
II section 4 certificate is required.

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

Report No.: SMO7665385
Certificate No.: CE573093

Accreditation granted by
Zentralstelle der Länder
für Sicherheitstechnik
ZLS
ZLS-ZQ-376/09

First Issue Date:
08 May 2001.

Based on periodical surveillance
this certificate is valid until
14 July 2016.

Current Issue Date: 01 August 2011

Certification Body



Appendix of EC-Certificate

(full quality assurance system)

according to annex II (excluding section 4) of Medical Devices Directive 93/42/EEC

Certificate No.: CE573093

Medical devices of the manufacturer:



Lützelwiesen 5
35428 Langgöns, Germany

Name of product	Variant	Item	UMDNS	Class
Databox DB 36	--	---	12-602	II a
Databox DB 23	---	---	12-602	II a
Neurowerk EMG (VAS 4)	---	---	11-614	II a

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ZLS

ZLS-ZQ-376/09

Darmstadt, 01 August 2011

EUROCAT Institute for Certification and Testing GmbH, 64295 Darmstadt, Germany,

Certification Body

page 1 of 1