



Product Service

# EC-CERTIFICATE

## Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 06 05 44132 005

**Manufacturer:** **EKF-diagnostic GmbH**

Ebendorfer Chaussee 3  
39179 Barleben / Magdeburg  
GERMANY

**Facility(ies):**

EKF-diagnostic GmbH  
Ebendorfer Chaussee 3, 39179 Barleben / Magdeburg,  
GERMANY

**Product**

**Category(ies):**

**Glucose control and regulation systems (CLAMP),  
Oxygen saturation sensors and monitors,  
Oxygen sensors and monitors**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

**Report No.:** 70112570

**Valid until:** 2011-11-26

**Date,** 2006-06-23

Reiner Krumme



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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