ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC-CERTIFICATE

Full Quality Assurance System

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

No. G1 07 07 56780 004

Manufacturer:

Biregs GmbH & Co. KG
Oberurseler Str. 70
61440 Oberursel/Ts.
GERMANY

Facility(ies):

Biregs GmbH & Co. KG
Oberurseler Str. 70, 61440 Oberursel/Ts., GERMANY

Product Category(ies):

Biofeedback Systems
L.I.F.E. System

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.: 71318590

Valid until: 2012-05-22

320510

Date, 2007-07-05

Reiner Krumme

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstrasse 65 · 80339 München · Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 10 04 56780 007

Holder of Certificate: **Biregs GmbH & Co. KG**
Oberurseler Str. 70
61440 Oberursel/Ts.
GERMANY

Facility(ies):
Biregs GmbH & Co. KG
Oberurseler Str. 70, 61440 Oberursel/Ts., GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Production and Service, Sales and Distribution of Biofeedback Systems and Light Therapy Devices**

Applied Standard(s):
EN ISO 13485:2003/AC:2007
Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke
Medical Devices - Quality Management Systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 71368558

Valid until: 2013-05-31

Date, 2010-06-01

Hans-Heiner Junker

378963

TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstraße 65 · 80339 München
Germany

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-999.98.12-46

TÜV®

ZAS / 03.09

BIREGS

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E-Mail: info@biregs.com
Internet: www.biregs.com

Wir

We

BIREGS GmbH & Co. KG

Oberurseler Straße 70

D – 61440 Oberursel

erklären in eigener Verantwortung, dass das Medizinprodukt

declare on our own responsibility that the medical device

L.I.F.E.-System

die Anforderungen der Richtlinie 93/42/EWG erfüllt.

meets the provisions of the Directive 93/42/EEC.

Angewendete Normen

Applied standards

EN 60601-1:1990+A1:1993+A2:1995 , EN 60601-1-2:2001+A1:2006.
EN 60601-1-A1:1996+A1:1999, EN ISO10993-5:1999

Benannte Stelle

Notified Body

TÜV Süd Product Service GmbH, Ridlerstraße 65 , D- 80339 München

Kenn-Nummer / Registration Number.	0123
Konformitätsbewertungsverfahren	Anhang II.3 MDD
Conformity Assessment Procedure:	Annex II.3 MDD

Diese Erklärung gilt für alle oben genannten Produkte, ab dem Datum der Unterschrift bis zum 31. Dezember 2010 und für die eine interne Freigabe vorliegt.

This Declaration applies to all above mentioned devices starting with the date of signature until 31. December 2010 and for which an internal release was given.

Die Technischen Unterlagen werden beim Hersteller aufbewahrt.

The technical data are kept by the manufacturer.

Oberursel, den 21.03.2010

Gebhard Weiler

Geschäftsführer / Managing Director

Version: 21032010005