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