



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 16 08 56780 013

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

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: 713084130

Valid from: 2016-08-18

Valid until: 2021-08-17



Date, 2016-08-18

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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