



Declaration of Conformity

Confirmation is hereby given that the software

BESA (BRAIN ELECTRICAL SOURCE ANALYSIS)

together with all options and modules, conforms to the basic requirements stipulated by the Council Directive regarding the harmonization of statutory requirements of the member states on Medical Devices 93/42/EEC (MDD). The Quality Management System meets the requirements of DIN EN ISO 9001:2000, and DIN EN ISO 13485:2003.

BESA is a product of class IIa according to MDD Annex IX. The conformity assessment was performed to Annex II MDD and confirmed by EC Certificate No. 1861824-006-000.

BESA is a Class A product according to IEC 62304:2006.

The product corresponds to UMDNS code 16-307 (GMDN 35163).

The product is marked with



specifying the Notified Body which carried out testing and certification:

LGA InterCert GmbH
Tillystraße 2
D-90431 Nürnberg

Aforesaid is issued with effect from July 2006 and under the sole responsibility of the manufacturer:

MEGIS SOFTWARE GMBH
Freihamer Str. 18
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Gräfelfing, March 25, 2008

Dieter Weckesser
Quality Management & Safety Responsible
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