



Declaration of Conformity

Confirmation is hereby given that the software

BESA® Epilepsy Version 1.0

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) as valid from 2010, March 21.

The Quality Management System meets the requirements of DIN EN ISO 9001:2008, and DIN EN ISO 13485:2007.

BESA Epilepsy 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.

Product evaluation was carried out according to DIN EN ISO 14971:2007 and to IEC 62304:2006 (categorized as class A product - no injury or damage to health is possible).

UMDNS code of BESA Epilepsy is: 16-307 (GMDN: 35163).

GMDN collective term is: CT112 Software, application program.

The product is marked with  1275

specifying the Notified Body which carried out certification:

LGA InterCert GmbH
Tillystraße 2
D-90431 Nürnberg, Germany

Aforesaid is issued with effect from March 2010 and under the sole responsibility of the manufacturer:

MEGIS SOFTWARE GMBH
Freihamer Str. 18
D-82166 Gräfelfing, Germany

Gräfelfing, March 21, 2010

A handwritten signature in blue ink that reads "Dieter Weckesser".

Dieter Weckesser
Quality Management & Safety Responsibility
MEGIS Software GmbH