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 13485:2010.

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. 1911810-006-000.

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

UMDNS code: 16-307 (GMDN: 35163).
GMDN collective term: CT112 Software, application program.

The product is marked with CE 1275

specifying the Notified Body which carried out certification:

LGA InterCert GmbH
Tillystraße 2
D-90431 Nuernberg, Germany

Aforesaid is issued under the sole responsibility of the manufacturer:

BESA GMBH
Freihamer Str. 18
D-82166 Graefelfing, Germany

Graefelfing, August 1, 2011

Dieter Weckesser
Quality Management & Safety Responsibility
BESA GmbH