



## Declaration of Conformity

Confirmation is hereby given that the software

**BESA<sup>®</sup> Epilepsy**  
**Version 2.0**

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).

The Quality Management System meets the requirements of DIN EN ISO 13485.

**BESA Epilepsy** is a product of class IIa according to MDD Annex IX rule 10 - 3 indent 3. The conformity assessment was performed to MDD Annex II excluding (4) and confirmed by EC Certificate No. HD 60092793 0001.

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



The number 0197 represents the identification number of the Notified Body:

TÜV Rheinland LGA Products 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, July 18, 2017

**Michael Kornweibel**  
Quality Management Responsibility  
BESA GmbH