



Declaration of Conformity

Confirmation is hereby given that the software

BESA[®] Research 7.0

June 2018

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 amended by Directive 2007/47/EC.

The Quality Management System meets the requirements of DIN EN ISO 13485:2012.

The conformity assessment was performed to MDD Annex II excluding (4) and confirmed by EC Certificate No. SX 60119570 0001.

BESA Research 7.0 June 2018 is a product of class IIa according to MDD Annex IX, rule 10, Indent 3.

Product Safety Class according to IEC 62304:2006/AMD1:2015: class A

UMDNS code: 16-307

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 declared under the sole responsibility of the manufacturer:

BESA GMBH

Freihamer Str. 18

D-82166 Graefelfing, Germany

This declaration is valid for all products with version number as mentioned above, or until withdrawn by BESA GmbH as manufacture due to modification of product or of requirements or of certificate.

Graefelfing, 31. July 2018

Michael Kornwebel

Quality Manager

BESA GmbH