



Declaration of Conformity

Confirmation is hereby given that the software

BESA[®] Research 7.1.2.1

together with all options and modules, conforms to the essential 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 conformity assessment was performed to MDD Annex II excluding (4) and confirmed by EC Certificate Registration No. HD 1785257-1.

The Quality Management System meets the requirements of DIN EN ISO 13485:2016.

BESA Research 7.1.2.1 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 B

UMDNS code: 16-307

GMDN collective term: CT112 Software, application program.

Basic UDI: 426236423BESAResFH

UDI-DI: (1)4262364230004

UDI-PI: (8012)07010201

The product is marked with



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

TÜV Rheinland LGA Products GmbH

Tillystraße 2

90431 Nuernberg, Germany

Aforesaid is declared under the sole responsibility of the manufacturer:

BESA GMBH

Freihamer Str. 18

82166 Graefelfing, Germany

Single Registration Number (SRN):

DE-MF-000020923

Graefelfing, July 7th, 2022

Michael Kornwebel

Quality Manager

BESA GmbH