Declaration of Conformity

Confirmation is hereby given that the software

BESA® MRI
Version 2.0 January 2017

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 13485:2012.
The conformity assessment was performed to MDD Annex II excluding (4) and confirmed by EC Certificate No. HD 60092793 0001.

BESA MRI is a product of class IIa according to MDD Annex IX rule 10 intend 3.

Product Safety Class according to DIN EN IEC 62304:2006 : class A - 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 0197

specifying the Notified Body which carried out certification:
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

This declaration is valid until withdrawn by BESA GmbH as manufacture due to modification of product or of requirements or of certificate.

Graefelfing, February 21, 2017

Michael Kornwebel
Quality Manager
BESA GmbH