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) as amended by Directive 2007/47/EC.

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

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

**BESA MRI** is a product of class Ila according to MDD Annex IX rule 10 indent 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: 12636 Physiologic monitoring system  
GMDN collective term: CT112 Software, application program.

The product is marked with ![CE 0197](image)

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  
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This declaration is valid for all products with version number as mentioned above, or until withdrawn by BESA Gmbh as manufacture due to modification of product or of requirements or of certificate.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, March 14, 2019

[Signature]

**Michael Kornwebel**  
Quality Manager  
BESA Gmbh