Declaration of Conformity

Confirmation is hereby given that the software

BESA® MRI 3.0

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 601363 14 000 1.
The Quality Management System meets the requirements of DIN EN ISO 13485:2016.

BESA MRI 3.0 is a product of class IIa according to MDD Annex IX, rule 10, indent 3.

Product Safety Class according to IEC 62304:2006+AMD2015: Class A

UMDNS code: 16-307 (GMDN: 12636 Physiologic monitoring system).
GMDN collective term: CT112 Software, application program.

The product is marked with CE 0197

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

This declaration is valid for all products with version number as mentioned above, including subversions, put onto markets as from date given hereafter, or until withdrawn by BESA GmbH as manufacturer due to modification of product or of requirements or of certificate.

Graefelfing, July 13th, 2020

Michael Kornwebel
Quality Manager
BESA GmbH