Declaration of Conformity

Confirmation is hereby given that the software

BESA® MRI 3.0.0.0

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 1785257-1.
The Quality Management System meets the requirements of DIN EN ISO 13485:2016.

BESA MRI 3.0.0.0 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

Basic UDI: 426236423BESAMRIB4
UDI-DI: (1)4262364230011
UDI-PI: (8012)030000000

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

Single Registration Number (SRN):
DE-MF-000020923

Graefelfing, July 7th, 2022

Michael Kornwebel
Quality Manager
BESA GmbH