



Declaration of Conformity

Confirmation is hereby given that the software

BESA[®] Connectivity 1.0

April 2018

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).

BESA Connectivity 1.0 is a product of class I according to MDD Annex IX, III. Classification, Rule 12.

Product Safety Class according to IEC 62304:2006/AMD1:2015 : class A - no injury or damage to health is possible.

UMDNS code: 17-222 Information System

GMDN: 17222 Information System

GMDN collective term: CT112Software, application program.

The product is marked with



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This declaration is valid for all products with version number as mentioned above, or until withdrawn by BESA GmbH as manufacture due to modification of product or of requirements.

Graefelfing, March 14, 2019

Michael Kornwebel

Quality Manager

BESA GmbH