



## Declaration of Conformity

Confirmation is hereby given that the software

### **BESA<sup>®</sup> Connectivity 1.0.1.0**

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 1.0.1.0** 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

UMDNS code: 17-222 Information System

GMDN: 17222 Information System

GMDN collective term: CT112 Software, application program

Basic UDI: 426236423BESAConD

UDI-DI: (1)426236423002

UDI-PI: (8012)0100010

The product is marked with



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 7<sup>th</sup>, 2022

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Quality Manager

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