Declaration of Conformity

Confirmation is hereby given that the software

BESA® 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

Graefelfing, July 7th, 2022

Michael Kornwebel
Quality Manager
BESA GmbH