



Declaration of Conformity

Confirmation is hereby given that the software

BESA[®] Statistics

Version 2.0

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).
The Quality Management System meets the requirements of DIN EN ISO 13485.

BESA Statistics is a product of class I according to MDD Annex IX rule 12.

The product is categorized as class A product according to IEC 62304 - no injury or damage to health is possible.

GMDN: 17222 Information System, inter-subject data comparison.
GMDN collective term: CT112 Software, application program.
UMDNS: 17-222 Information System, inter-subject data comparison.

The product is marked with



Aforesaid is issued under the sole responsibility of the manufacturer:

BESA GMBH
Freihamer Str. 18
D-82166 Graefelfing, Germany

This conformity declaration is valid for all versions put into market starting with the date given below.

Graefelfing, July 28, 2015

Dieter Weckesser
Quality Management & Safety Responsibility
BESA GmbH