



Declaration of Conformity

Confirmation is hereby given that the software

BESA® Statistics **Version 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).

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

BESA Statistics is a product of class Im according to MDD Annex IX rule 12. The conformity assessment was performed to MDD Annex II excluding (4), and confirmed by EC Certificate No. HD 60092793 0001.

Product evaluation was carried out according to DIN EN ISO 14971 and to IEC 62304 (categorized as class A product - no injury or damage to health is possible).

GMDN: 17222 Information System, inter-subject data comparison.

GMDN collective term: CT112 Software, application program.

The product is marked with



specifying the Notified Body which carried out certification:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
D-90431 Nuernberg, Germany

Aforesaid is issued under the sole responsibility of the manufacturer:

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

Graefelfing, March 26, 2015

Dieter Weckesser

Quality Management & Safety Responsibility
BESA GmbH