



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) as valid from 2010, March 21.
The Quality Management System meets the requirements of DIN EN ISO 9001:2008, and DIN EN ISO 13485:2010.

BESA Statistics is a product of class IIa according to MDD Annex IX. The conformity assessment was performed to Annex II MDD and confirmed by EC Certificate No. 1911810-006-000.

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  1275

specifying the Notified Body which carried out certification:

LGA InterCert 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, December 13, 2011

Dieter Weckesser
Quality Management & Safety Responsibility
BESA GmbH