

DECLARATION OF CONFORMITY
QUALITY SYSTEM DOCUMENT

Manufacturer: Elekta Business Area Software Systems
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Products: Ergo++ Radiation Treatment Planning Software, Model
9600- All

Classification: IIb, Rule 9

Risk Classification: Council Directive 93/42/EEC, Annex IX II (2.3) and III (3.1) [Rule 9]

We herewith declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EC for medical devices, as well as all applicable International embodiments of the Directive. All supporting documentation is retained under the premises of the manufacturer.

Conformity Assessment procedure for CE –marking: Council Directive 93/42/EEC, Annex II (3.2).

Standards Applied:
ISO 9001:2008, EN ISO 13485:2003, ISO 14971:2003, EN 62083:2001, EN 61217:1996, EN 980:2008, IEC 62304:2006

Notified Body/Number: BSI 0086

EC Certificates: 553751
ISO 13485 (Including CMDCAS) FM77312

Start of CE Marking: June 2009

Place, Date of Issue: St. Louis, MO 63043 USA , Effective 26 Oct 2009

Certification:



Thomas H. Faris, Elekta BASS Management Representative