

**DECLARATION OF CONFORMITY**  
**QUALITY SYSTEM DOCUMENT**

Manufacturer: Elekta Business Area Software Systems  
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Products: Brachytherapy Treatment Planning System, Interplant iTPS,  
iTGS, iPAS, Interplant Laptop Cart, POC Cart Part Number  
1-1939

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 980:2008

Notified Body/Number: BSI 0086  
EC Certificates: 553751  
ISO 13485 (Including CMDCAS) FM77312  
Start of CE Marking: December, 1995

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

Certification:

  
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Thomas H. Faris, Elekta BASS Management Representative