

DECLARATION OF CONFORMITY
QUALITY SYSTEM DOCUMENT

Manufacturer: Elekta Business Area Software Systems
IMPAC Medical Systems, Inc.
100 Mathilda Place, 5th Floor
Sunnyvale, California, USA 94086

European Representative: CEpartner4U, Esdoornlaan 13,
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Product: MOSAIQ
(including, but not limited to, SEQUENCER,
MLCFit and ViewStation which were previously
CE marked)

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
ISO 13485:2003
ISO 14971:2007

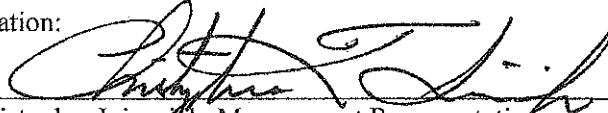
Notified Body/Number: BSI Product Service/0086

EC Certificates: CE 77310

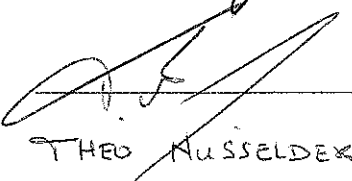
Start of CE Marking: 8/10/10 (MOSAIQ)

Place, Date of Issue: Sunnyvale, CA, 10 August, 2010

Certification:



Christopher Ivcey, Management Representative



THEO NUSSELDER, CEPartner4U DIRECTOR