

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.****CE 553751**

## Issued To:

**Elekta Business Area Software Systems  
IMPAC Medical Systems, Inc.  
13723 Riverport Drive, Suite 100  
Maryland Heights  
Missouri  
63043  
USA**

In respect of:

**The design, development and manufacture of oncology software systems to support radiotherapy and chemotherapy diagnosis, treatment planning and treatment delivery, including charting, imaging, and picture archiving & communications.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **26 October 2009**Date: **28 June 2016**Expiry Date: **25 October 2019**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.  
This certificate was issued electronically and is bound by the conditions of the contract.

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Missouri  
63043  
USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
3D Line Research and Development S.r.l. Centro Direzionale Colleoni Palazzo Andromeda, ING. 3 Agrate Brianza (MB) 20864 Italy	<b>Development</b>
Elekta Business Area Software Systems CMS Worldwide Corp. Pangu Plaza, Office Building, Block A No. 27 Fourth Ring Mid Road Chaoyang District 100101 Shanghai China	<b>Development</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Elekta Limited Linac House Fleming Way Crawley West Sussex RH10 9RR United Kingdom	<b>EU Representative</b>

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# EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
26 October 2009	7438842	First Issue. Transfer from another Notified Body
30 April 2012	7806891	Certificate reissue due to scope clarification and change of legal manufacturer name from Computerized Medical Systems, Inc. to IMPAC Medical Systems, Inc., AKA IMPAC, Inc. Change of EU Representative from Paul Shane Bennetts to Elekta Limited, Crawley, UK
01 October 2014	8195437	Certificate renewal and change of address of Elekta BASS site in Shanghai from 455 Fushan Road, Pudong Area to No. 27 Fourth Ring Mid Road, Chaoyang District
28 June 2016	8524077	Change of address for significant subcontractor 3D Line Research and Development S.r.l. from Via Bernado Rucellai 23, 20126 Milano, Italy to Centro Direzionale Colleoni, Palazzo Andromeda, ING.3, 20864 Agrate Brianza (MB) The legal manufacturer's name was revised to remove "AKA IMPAC, Inc."

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