

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 566690
Issued To: **BioVision Technologies, LLC**
221 Corporate Circle, Suite H
Golden
Colorado
80401
USA

In respect of:

The manufacture and final inspection of sterile arthroscopic instruments, single use Epidural Catheter Kits and non-sterile re-usable epidural endoscopes

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **14 February 2011**

Date: **11 February 2016**

Expiry Date: **13 February 2021**

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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:

Certificate No: **CE 566690**
Date: **11 February 2016**
Issued To: **BioVision Technologies, LLC**
221 Corporate Circle, Suite H
Golden
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80401
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Subcontractor:	Service(s) supplied
Emergo Europe Molenstraat 15 2513 BH, The Hague Netherlands	EU Representative
Lake Region Medical 13024 North Main Street Trenton GA 30752 USA	Warehousing
Lake Region Medical 365 South Industrial Blvd Trenton GA 30752 USA	Manufacture

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Subcontractor:	Service(s) supplied
Pro-Tech Design & Manufacturing, Inc. 14561 Marquardt Avenue Santa-Fe Springs California 90670 USA	Assembly Packaging
Shanghai Xuhua Optics Ltd 3/F, Building 3 No. 33, Jianyun Road Pudong New District Shanghai 200120 China	Assembly
STERIS Isomedix Services 43425 Business Park Drive Temecula California 92590 USA	ETO Sterilization

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 566690**
 Date: **11 February 2016**
 Issued To: **BioVision Technologies, LLC
 221 Corporate Circle, Suite H
 Golden
 Colorado
 80401
 USA**

Date	Reference Number	Action
14 February 2011	7574981	First issue.
28 March 2014	8029101	Extension to scope to include epidural catheter kits. Addition of 'Accellent Inc' as subcontractor for manufacturing; correction of a typo in subcontractor 'Shanghai Xuhua Optics Ltd'.
11 February 2016	8482551	Certificate Renewal. Scope extension to include non-sterile reusable epidural endoscopes. Changes to sub-contractors: Address change for Shanghai Xuhua Optics Ltd, Name and activity changes for Lake Region Medical 13024 North Main Street, Addition of Lake Region Medical 365 South Industrial Blvd.