

# EC Certificate - Full Quality Assurance System

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

**No.** CE 546761  
**Issued To:** **AccuVein Inc.**  
**3243 Route 112,**  
**Building 1, Suite 2**  
**Medford**  
**New York**  
**11763**  
**USA**

In respect of:

**Design and manufacture of non-invasive infrared based visualization devices for the purpose of observing the location of veins.**

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2009-06-23**

Date: **2019-03-08**

Expiry Date: **2024-03-06**

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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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

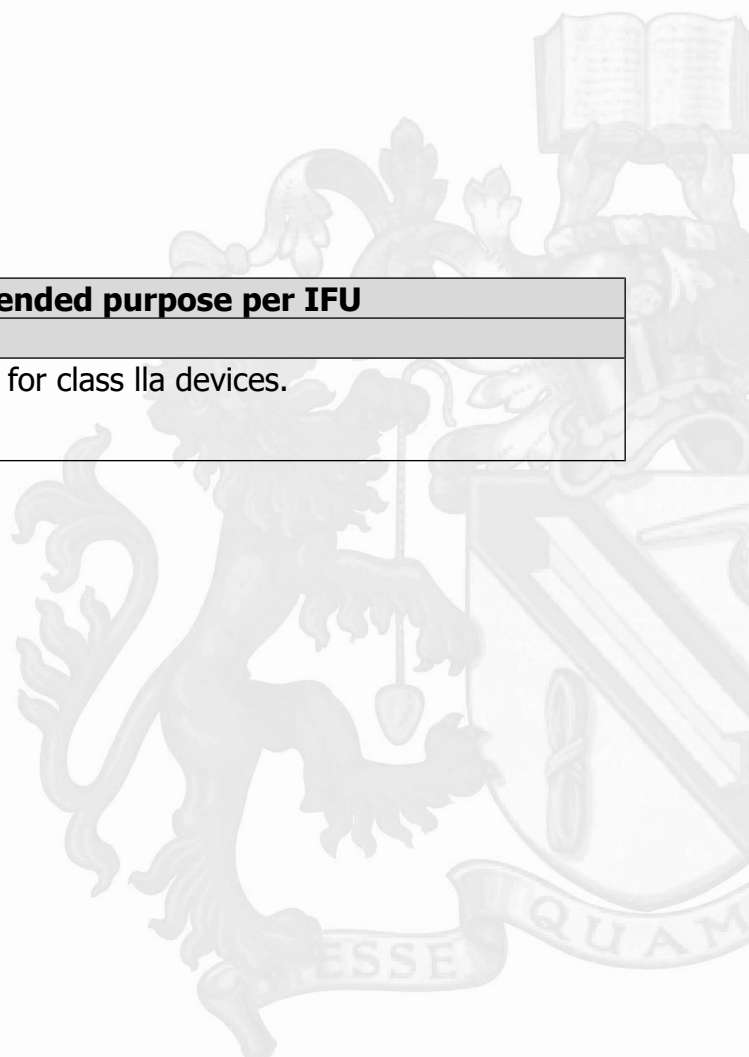
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## Supplementary Information to CE 546761

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| NBOG Code        | Device Name  | Intended purpose per IFU   |
|------------------|--|----------------------------|
| <b>Class IIa</b> |  |                            |
| MD 1202          | AccuVein AV300<br>AccuVein AV400<br>AccuVein AV500 | N/A for class IIa devices. |



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## List of Significant Subcontractors

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

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**USA**

| <b>Subcontractor:</b>   | <b>Service(s) supplied</b>  |
|---|---|
| AccuVein Inc.<br>3475 Edison Way, Suite E<br>Menlo Park<br>California<br>94025<br>USA       | <b>Design</b><br><b>Development</b><br><b>Manufacture</b><br><b>Regulatory Compliance</b> |
| Benchmark Electronics Inc.<br>4065 Theurer Boulevard<br>Winona<br>Minnesota<br>55987<br>USA | <b>Manufacture</b>  |
| Emergo Europe<br>Prinsessegracht 20<br>2514 AP The Hague<br>The Netherlands                 | <b>EU Representative</b>  |

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 546761**  
 Date: **2019-03-08**  
 Issued To: **AccuVein Inc.  
 3243 Route 112,  
 Building 1, Suite 2  
 Medford  
 New York  
 11763  
 USA**

| Date            | Reference Number | Action   |
|-----------------|------------------|--|
| 23 June 2009    | 7317834          | First Issue  |
| 14 October 2011 | 7753746          | Certificate reissue due to change of company name from AccuVein LLC to AccuVein Inc.   |
| 09 June 2014    | 8120895          | Certificate renewal. Clarification of scope wording. Certificate upgraded from an Annex V to an Annex II   |
| 06 March 2019   | 9719937          | Certificate Renewal. Change of legal manufacturer address. Change of EU representative address. Addition of Accuvein Inc., Menlo park (CA) to the list of significant subcontractors. Addition of devices table. |
| Current         | 7782123          | Traceable to NB 0086   |

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