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**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 546761

Issued To:

AccuVein Inc.
3243 Route 112,
Building 1, Suite 2
Medford
New York
11763
USA

NBOG Code	Device Name	Intended purpose per IFU
Class IIa		
MD 1202	AccuVein AV300 AccuVein AV400 AccuVein AV500	N/A for class lla devices.

First Issued: **2009-06-23** Date: **2019-03-08** Expiry Date: **2024-03-06**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

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

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

...making excellence a habit.™

By Royal Charter

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