

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.**
40 Goose Hill Road
Cold Spring Harbor
New York
11724
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 0086):



Gary Fenton, Global Assurance Director

First Issued: **23 June 2009**

Date: **09 June 2014**

Expiry Date: **22 June 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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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:

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Subcontractor:

Service(s) supplied

Benchmark Electronics Inc
Minnesota Division
3535 Technology Drive
Rochester
Minnesota 55901
USA

Manufacture

Emergo Europe
Molenstraat 15
2513 BH The Hague
Netherlands

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 546761**
Date: **09 June 2014**
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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

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