



Certificate

Production Quality Assurance

No. CE 543548



Issued to:

**Three Palm Software
16 Yankee Point Drive
Carmel
California
93923
USA**

In respect of:

The manufacture of breast imaging software devices and those aspects of Annex V concerned with the metrological requirements of breast imaging software devices

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

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

Gary Fenton, Global Assurance Director

First Issued: **29 Jan 2009**

Date: **2 Dec 2013**

Expiration Date: **28 Jan 2019**

Page: 1 of 1

Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

...making excellence a habit.™



List of Significant Subcontractors

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

Certificate No. **CE 543548**
Date: **2 Dec 2013**
Issued to: **Three Palm Software**
Carmel, California
USA

Subcontractor**Service(s) supplied**

Wellkang Ltd
trading as Wellkang Tech Consulting
Suite B, 29 Harley Street
London
W1G 9QR
United Kingdom

EU Representative



History of Quality Assurance Certificate

Certificate No: **CE 543548**
Date: **2 Dec 2013**
Issued to: **Three Palm Software**
Carmel, California
USA

Date	Reference Number	Action
29 January 2009	7287834	First Issue
02 December 2013	8064654	Certificate renewal. Change of manufacturer address from 367 Penn Way, Los Gatos to 16 Yankee Point Drive, Carmel. Extension to scope due to the reclassification of a breast imaging software device from Class IIa to Class I measuring. Addition of EU Representative.