

EC Certificate - Product Quality Assurance

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

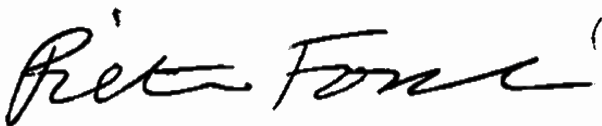
No. CE 607108
Issued To: **Micrima Ltd**
Engine Shed
Station Approach
Temple Meads
Bristol
BS1 6QH
United Kingdom

In respect of:

Final inspection and test of diagnostic breast imaging systems using RF vector analysis technology.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex VI. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb products, an Annex III certificate is required.

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



Pietro Foschi - Strategic Delivery Director

First Issued: **23 March 2015**

Date: **23 March 2015**

Expiry Date: **22 March 2020**

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Page 1 of 1

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 VI

List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
LMW Electronics, Ltd Unit 4, Newtown Grange Farm Business Park, Desford Road Newtown Unthank Leicestershire LE9 9FL United Kingdom	Testing
Rimer-Alco (AKA I4 Innovations) 4-8 Kelvin Place Stephenson Way Thetford Norfolk IP24 3RR United Kingdom	Testing

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EC Certificate - Product Quality Assurance Certificate History

Certificate No: CE 607108
Date: 23 March 2015
Issued To: Micrima Ltd
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Date	Reference Number	Action
23 March 2015	8073132	Initial Issue

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Page 1 of 1

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