

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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **23 March 2015**

Date: **16 May 2016**

Expiry Date: **22 March 2020**

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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.