

EC Certificate - Product Quality Assurance

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

No.**CE 607108**

Issued To:

**Micrima Ltd
One Glass Wharf
Bristol
BS2 0EL
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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-03-23**Date: **2020-03-17**Expiry Date: **2024-05-26**

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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.

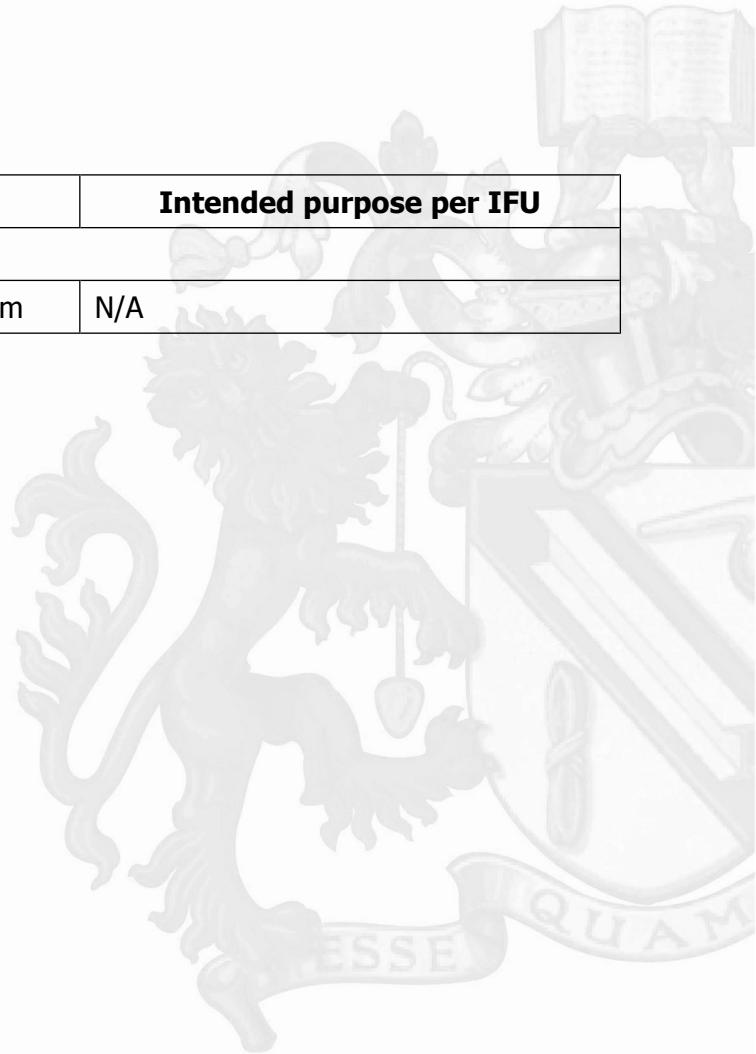
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Supplementary Information to CE 607108

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD1202	MARIA® Breast Imaging System	N/A



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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

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

Certificate No: **CE 607108**
Date: **2020-03-17**
Issued To: **Micrima Ltd**
One Glass Wharf
Bristol
BS2 0EL
United Kingdom

Subcontractor:

Service(s) supplied

Custom Interconnect Ltd
CIL House
Charlton Road
Andover
Hampshire
SP10 3JL
United Kingdom

Testing

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EC Certificate - Product Quality Assurance Certificate History

Certificate No: **CE 607108**
 Date: **2020-03-17**
 Issued To: **Micrima Ltd**
One Glass Wharf
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Date	Reference Number	Action
23 March 2015	8073132	Initial Issue
16 May 2016	8521350	Removal of LMW Electronics and Rimer-Alco from subcontracter Addition of Custom Interconnect Ltd.
21 February 2019	8935552	Traceable to NB 0086.
Current	3108373	Renewal. Added device table.

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