

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 695495
Issued To: **MEIK Limited**
Unit 1110, 11/F., Block A,
Ming Pao Industrial Centre
18 Ka Yip Street
Chai Wan
Hong Kong

In respect of:

The design and manufacture of an electrical impedance tomography device for adult females mammography in a symptomatic setting as an adjunct modality.

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-06-12**

Date: **2019-06-12**

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 695495

Issued To:

MEIK Limited
Unit 1110, 11/F., Block A,
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NBOG	Device Name	Intended purpose per IFU
Class IIa		
MD 1202	MEIK® Electrical impedance mammograph.	To detect various abnormality that occur in the mammary gland in women such as cancer, fibrocystic disease, mastitis, physiological involution, and others.

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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:

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Hong Kong

Subcontractor:	Service(s) supplied
PGT 3 Chemin de Meursault, 21190 Auxey Duresses France	EU Representative
PKF "SIM-TECHNIKA" Ltd 2 Chkalova St., Office 223, Yaroslavl 150004 Russian Federation	Design Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 695495**
 Date: **2019-06-12**
 Issued To: **MEIK Limited**
Unit 1110, 11/F., Block A,
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Date	Reference Number	Action
Current	8960763	First issue.

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