

EC Certificate - Full Quality Assurance System

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

No. CE 654813
Issued To: **ImpediMed Limited**
Unit 1
50 Parker Court
Pinkenba
Queensland
4008
Australia

In respect of:

Design and manufacture of bioimpedance devices for determining body composition parameters including fluid status for assisting in the diagnosis of lymphoedema.

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **13 September 2016**

Date: **13 September 2016**

Expiry Date: **10 March 2019**

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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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List of Significant Subcontractors

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

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50 Parker Court
Pinkenba
Queensland
4008
Australia**

Subcontractor:	Service(s) supplied
ImpediMed Incorporated 5900 Pasteur Court Suite 125 Carlsbad California 92008 USA	Design Distribution Sales Warehousing
MediMark Europe Sarl 11 Rue Emile Zola BP 2332 38033 Grenoble Cedex 2 France	EU Representative
SRX Global 8-10 Kitchen Road Dandenong Victoria 3175 Australia	Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 654813**
Date: **13 September 2016**
Issued To: **ImpediMed Limited
Unit 1
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Pinkenba
Queensland
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Date	Reference Number	Action
14 September 2016	8542699	First issue. Transfer from another Notified Body.

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