Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Conformity Assessment Certificate

Product Quality Assurance Procedures

This is to certify that the quality management system described below complies with the relevant provisions of Schedule 3, Part 5 of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Certification is based on an assessment of the Product Quality Management System for final inspection and testing to ensure that each medical device to which the system is applied conforms to the type described in the scope of the respective Type Examination certificate (Schedule 3, Part 2) or is in accordance with the technical documentation prepared by the manufacturer under Schedule 3, clause 6.4.

Manufacturer Name: ImpediMed Limited

Manufacturer Address: Unit 1, 50 Parker Court
Pinkenba, Queensland 4008
Australia

Commencement Date: 19 October 2012

Certificate Expiry Date: 19 October 2017

This certificate has effect at all times from the commencement date, until the end of the period specified in the certificate (expiry date), or unless it has been suspended or revoked.

This certificate is issued under Section 41EE of the *Therapeutic Goods Act 1989* by:

John Skinner
Delegate of the Secretary
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia

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Scope of Certificate

Device Categories

	Description	Limitations (if applicable)
1.	Fat/lean analysers and accessories	

Critical Suppliers

	Name and Address	Scope
1.	Intellidesign Pty Ltd 99 Bluestone Circuit Seventeen Mile Rocks, QLD, 4073 Australia	Design and development
2.	SRXGlobal 8–10 Kitchen Road Dandenong, VIC, 3175 Australia	Production
3.	IV&V Australia Pty Ltd Suite 3, 385 Pacific Highway Crows Nest, NSW, 2065 Australia	Software validation
4.	TÜV SÜD PSB Pte Ltd Testing Group—Electrical & Electronics 1 Science Park Drive Singapore 118221	Electromedical safety testing
5.	Vermed Inc 9 Lovell Drive Bellows Falls, VT, 05101 United States of America	Electrode design and production

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Certificate History

Version	Details	Issue Date	File Reference
1	Initial certification	15 January 2007	2006/050995
2	Change of address From: Building 4B, Garden City Office Park 2404 Logan Road Eight Mile Plains Queensland 4113 Australia To: Unit 1, 50 Parker Court Pinkenba, Queensland 4008 Australia	07 October 2009	2009/003817
3	Extension of validity and reformatting of certificate	08 February 2012	2012/000180
4	Recertification and update to list of suppliers	19 October 2012	2012/000180
Certificate Location (Manufacturer Root File Number):			2010/010675

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Conditions

The following conditions apply automatically under Section 41EJ of the *Therapeutic Goods Act 1989*:

Entry and inspection powers

(1) A conformity assessment certificate is subject to the conditions that the manufacturer in respect of whom the certificate is issued will:
  (a) allow an authorised person:
    (i) to enter, at any reasonable time, premises (including premises outside Australia) at which the person or any other person deals with medical devices of a kind covered by the certificate; and
    (ii) while on those premises, to inspect those premises and medical devices of any kind on those premises and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of medical devices of any kind on those premises or any thing on those premises that relates to medical devices of any kind; and
    (iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and
  (b) if requested to do so by an authorised person:
    (i) produce to the person such documents relating to devices of a kind covered by the certificate, or to the manufacturer's quality management system, as the person requires; and
    (ii) allow the person to copy the documents.

Review

(2) A conformity assessment certificate is subject to the condition that the manufacturer in respect of whom the certificate is issued will cooperate in any review by the Secretary of the certificate to determine whether the conformity assessment procedures relating to the following matters have been applied to the kinds of medical devices covered by the certificate:
  (a) the application of quality management systems for the manufacture of medical devices;
  (b) the certification of compliance with the essential principles;
  (c) any other requirement of the conformity assessment procedures specified in the regulations made for the purposes of subsection 41EC(2).

Notification of substantial changes

(3) A conformity assessment certificate is subject to the condition that the person in respect of whom the certificate is issued will notify the Secretary, in writing, of any plan for substantial changes to:
  (a) quality management systems; or
  (b) the product range covered by those systems; or
  (c) the product design of kinds of medical devices;
  in respect of which the certificate is issued.

Fees

(4) A conformity assessment certificate is subject to the condition that the applicant for the certificate will pay a fee, prescribed in the regulations, for a review under subsection (2), when the fee becomes due and payable.

(5) The regulations may prescribe different levels of fees for different kinds of manufacturers and medical devices.

Conditions in regulations

(5A) A conformity assessment certificate is subject to any conditions prescribed by the regulations for the purposes of this subsection.

Conditions do not limit other conditions

(6) A condition imposed under this section is in addition to any conditions imposed under this Division.