Certificate Number
AU Q00212

Australian Government

Department of Health
Therapeutic Goods Administration

Conformity Assessment Certificate

Full Quality Assurance Procedures

This is to certify that the quality management system described below complies with the relevant provisions of Schedule 3, Part 1 (excluding clause 1.6) of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Certification is based on an assessment of the Full Quality Management System, applied at each stage of medical device manufacture, from the design of a device until its final inspection before being supplied.

Manufacturer Name: Cellplex Pty Ltd

Manufacturer Address: 16-18 Hydrive Close
DANDENONG SOUTH VIC 3175
Australia

Commencement Date: 21 February 2014

Certificate Expiry Date: 05 February 2019

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:

Benno Schmidhauser
Signed electronically
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.	Tube, blood collection, open	
2.	Reservoir, blood, cardiopulmonary bypass	
3.	Filter, heart-lung bypass unit, priming solution	
4.	Transducer, pressure, dome, single use	
5.	Sensor, blood gas, cardiopulmonary bypass, in-line	
6.	Adaptor, shunt	
7.	Clamp, surgical, tubing, single use	
8.	Filter, blood, cardiopulmonary bypass	
9.	Valve, backflow, in-line, single use	
10.	Valve, stopcock, general-purpose	
11.	Cover, cable/lead/sensor/probe	
12.	Intravenous administration set, general-purpose	
13.	Syringe, general-purpose	
14.	Bag, urine collection, open-ended, non body worn	
15.	Needle, airway	
16.	Port, injection, catheter	
17.	Filter, gas, delivery line	
18.	Scissors, general-purpose	
19.	Drape, surgical, general purpose, single use	
20.	Adaptor, pin-indexed, single use	
21.	Tubing set, heart-lung bypass	

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Sterilisation of Systems and Procedure Packs

	Description	Limitations (if applicable)
1.	Sterilisation of systems and procedures packs, where the manufacturer has applied the conformity assessment procedures under Regulation 3.10, and Schedule 3, clause 7.5 of the Therapeutic Goods (Medical Devices) Regulations 2002.	This scope is limited to the process of sterilising systems and procedure packs; it does not cover any other provisions of the regulations such as whether the system and procedure packs have been put together in accordance with Schedule 3, clause 7.5.

Critical Suppliers

	Name and Address	Scope
1.	Steritech Pty Ltd 160 South Gippsland Highway Dandenong South VIC 3175 Australia	Ethylene oxide sterilization
2.	ITL Healthcare Pty Ltd 1/63 Wells Road Chelsea Heights VIC 3196 Australia	7-day heated aeration after ethylene oxide sterilisation

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Certificate History

Version	Details	Issue Date	File Reference
1	Initial certification	20 February 2009	2007/004481 & 2009/001568
2	Changes to • the sterilization process from half cycle to full cycle • addition of supplier, ITL Healthcare, for 7-day heated aeration process after ethylene oxide sterilisation	25 June 2013	2012/012047
3	Recertification and reformatting of additional conditions. Removal of manufacturing facility as same as manufacturer address.	06 February 2014	2013/004099
4	Change to critical supplier name: ITL	21 February 2014	2013/004099
Certificate Location (Manufacturer Root File Number):			2010/010624

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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.