Australian Government

Department of Health
Therapeutic Goods Administration

Quality Management System Certificate

ISO 13485:2003

Issued to:

Cellplex Pty Ltd

This is to certify that the Quality Management System for the design, development and manufacture of the devices described below conforms to the relevant provisions of ISO13485:2003.

TGA File Number:	2012/022973
Manufacturer Name:	Cellplex Pty Ltd
Manufacturer Address:	16-18 Hydrive Close, Dandenong South VIC 3175 AUSTRALIA
Facility Address:	16-18 Hydrive Close, Dandenong South VIC 3175 AUSTRALIA
Scope of Certification:	The manufacture of sterile medical devices (i.e., tubing sets, shunts, drapes, intravenous administration sets, syringes, urine collection bags, needles, ports. scissors, and adaptors), and 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.
Special Conditions:	Nil

Effective Date: 20 February 2014

Expiry Date: 14 January 2016

This Certificate is valid for the period indicated subject to periodic and satisfactory surveillance.

20 February 2014

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Merryn Hagan
Senior Inspector
Office of Manufacturing Quality
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: +61 (0)2 6221 6856
Fax: +61 (0)2 6232 8426

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Date

MI-2011-CE-05361-3

This Certificate is the property of the Office of Manufacturing Quality, TGA, and must be returned upon demand.