



Certificate Number
AU Q00216

Australian Government

Department of Health
Therapeutic Goods Administration

Conformity Assessment Certificate

Production Quality Assurance Procedures

This is to certify that the quality management system described below complies with the relevant provisions of Schedule 3, Part 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Certification is based on an assessment of the Production Quality Management System for production and final inspection 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: BMDi TUTA Healthcare Pty Limited

Manufacturer Address: Unit 4B 128-130 Frances Street
LIDCOMBE NSW 2141
Australia

Commencement Date: 21 February 2014

Certificate Expiry Date: 20 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