Certificate Number
MRA Q00088

Australian Government

Department of Health
Therapeutic Goods Administration

EC Certificate

Production Quality Assurance Procedures

Annex V of Directive 93/42/EEC on Medical Devices

This is to certify that the quality management system described below conforms to the relevant provisions of Annex V of the Council Directive 93/42/EEC on medical devices. Certification is based on an examination of the Quality Management System for production and final inspection to ensure that each medical device to which the system is applied conforms to the product described in the Type Examination or the technical documentation as applicable.

Manufacturer Name:	BMDi TUTA Healthcare Pty Limited
Manufacturer Address:	Unit 4B 128-130 Frances Street LIDCOMBE NSW 2141 Australia
Commencement Date:	05 September 2014
Certificate Expiry Date:	20 February 2019
Associated CA Certificate	AU Q00216

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. Its validity is dependent on the currency of the associated CA Certificate listed above.

This certificate is issued by:

Peter Kaylock
Signed electronically
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606
Australia

Notified Body
Identification Number
0805