

## **Declaration of Conformity**

This is a declaration made in accordance with the requirements of clause 6.6 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulation 2002 relating to the stated devices.

Name

**Qlicksmart Pty Ltd** 

**Address** 

Level 1, Boundary Street, West End, Brisbane, QLD 4101 Australia

**Medical Device** 

Qlicksmart Scalpel Blade Remover

Classification

Class I Sterile

**GMDN Code** 

46236, Preferred Term

Scope of Application:

All

Certification

AU Q00075, Section 41EE of the Therapeutic Goods Act 1989

Each kind of medical device complies with the applicable provisions of the essential principles and the classification rules before being shipped.

Standards applied:

EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied Part 1: General requirements, EN ISO 14971:2012 Medical devices – Application of risk management to medical devices, EN 1041:2008 Information supplied by the manufacturer with medical devices, AS/NZS 3825:1998 Procedures and devices for the removal of scalpel blades from scalpel handles

Authorized Signatory:

Dr. Michael Sinnott (Managing Director)

Date: 18/11/17

Brisbane

Qlicksmart Pty Ltd (ABN 37 033 096 995) PO Box 5677, West End, Brisbane, QLD 4101, Australia Level 1, 148, Boundary Street, West End, Brisbane, QLD 4101, Australia