

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.

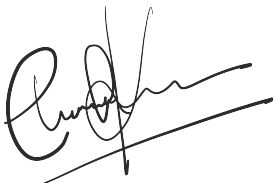
Name : Qlicksmart Pty Ltd
Address : Level 1, Boundary Street, West End, Brisbane, QLD 4101 Australia
Medical Device : Qlicksmart Scalpel Blade Remover
Classification : Class I
GMDN Code : 46235 (TGA Listing GMDN 38442), Preferred Term
Scope of Application: See Annex I to Declaration of Conformity
Certification : 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 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes, **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 14971:2019** 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:



For Qlicksmart Pty Ltd
Dr. Chamindika Konara (General and QA Manager)
Date: 17th February 2021
Brisbane, Australia