

Declaration of Conformity

Manufacturer:

Qlicksmart Pty Ltd

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

We, the manufacturer, herewith declare that the products
Qlicksmart SnapIT ampoule openers
meet the provisions of the following standards.

Standards And Directives applied:

- EN ISO 13485:2016 Medical Devices – Quality Management System
- EN ISO 14971:2012, Medical Devices – Application of Risk Management to Medical Devices
- EN 1041:2008 Information supplied by the manufacturer with medical devices
- 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.

This declaration is valid in connection with the release of documents for the respective batched of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of
Qlicksmart Pty Ltd
Level 1, 148 Boundary Street, West End, Brisbane, Qld 4101 Australia



For Qlicksmart Pty Ltd
Dr. Michael Sinnott (Managing Director)

Date: 24/05/2017

Brisbane