www.qlicksmart.com
+61 7 3844 1182 T
+61 7 3844 1183 F

EU Declaration of Conformity
(Annex IV, European Medical Device Regulation (EU) 2017/745)

Manufacturer:
Qlicksmart Pty Ltd
Level 1, 148 Boundary Street, West End,
Brisbane, QLD 4101 Australia

Whose single Authorized Representative:
Donawa Lifescience
Piazza Albania, 10
00153 Rome, Italy

We, the manufacturer, herewith declare that the products
Qlicksmart Scalpel Blade Removers, GMDN code 46235, preferred term, meets the provisions of Regulation (EU) 2017/745 which apply to them.

Basic UDI-DI numbers are included in Annex 1 to Declaration of Conformity.

The medical device has been assigned to Class I according to Annex VIII of the Regulation (EU) 2017/745. It bears the CE mark.

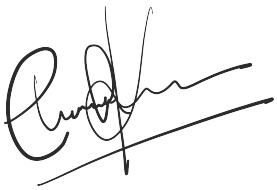
We hereby declare that the above-mentioned devices comply with Regulation (EU) 2017/745 and are designed and manufactured under production quality assurance according to Annex IV of the Regulation.

Standards applied:

- EN ISO 13485:2016 Medical devices – Quality management system
- EN ISO 14971:2019 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

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. Chamindika Konara (General and QA Manager)
Date: 17th February 2021
Brisbane, Australia

Annex 1 to Declaration of Conformity

Refer below for Basic UDI-DI information related to Qlicksmart Scalpel Blade Removers:

Trade name	Product code	Basic UDI-DIs
BladeFLASK	QFYGEN	09337363001247
	QFYUKGEN	09337363001278
	QFYUKSM	09337363001285
BladeBOX	QBB2Y	09337363001254
BladeFlask EVO	QBVYGEN	09337363001759
	QBVYUKGEN	09337363001773
	QBVYUKSM	09337363001797