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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 Single-Use Scalpel Blade Removers, Non-sterile. 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.

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

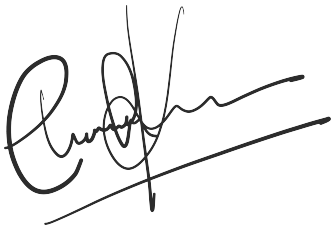
We hereby declare that the above-mentioned devices comply with European Medical Device Regulation 2017/745 and are designed and manufactured under production quality assurance according to Annex XI of the Regulation.

Standards applied include but not limit to the following standards:

- 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
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 Single-Use Scalpel Blade Removers, Non-sterile:

Trade name	Product code	Basic UDI-DIs
BladeSINGLE	QSBS01-B	09337363001704
BladeCASSETTE	QSSVCAS-BY	09337363000516
BladeNeedleSYSTEM	QBNS202B	09337363001728
BladeCARTRIDGE	QSSVCAT-1B	09337363001711