

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
SRN: AU-MF-000033870

Whose single Authorized Representative:
Donawa Lifescience
Piazza Albania, 10
00153 Rome, Italy
SRN: IT-AR-000007785

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 number is included in Annex 1 of Declaration of Conformity, as well as the GTIN-14
number applicable to this family.

The medical device has been assigned to Class I according to section 1 of Article 2 and Annex VIII
of the Medical Device Regulation (EU) 2017/745. It bears the CE mark.

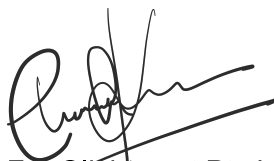
We hereby declare that the Technical Documentation for the above-mentioned devices complies
with the requirements set forth in article 52(7), article 19, Annexes II and III of the Medical Device
Regulation (EU) 2017/745 for Class I devices.

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 ISO 20417:2021, Medical Devices - Information to be supplied by the manufacturer
- EN ISO 15223-1:2021, Medical devices – Symbols to be used with information to be
supplied by the manufacturer, 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 Manager)
Date: 03rd March 2023
Brisbane, Australia

Annex 1 to Declaration of Conformity

Basic UDI-DI number for Qlicksmart Scalpel Blade Removers, only applicable for EU MDR 2017/745, is **3373630QSBRFL00001PQ**

Trade name	Product code	UDI-DI (GTIN-14) Number
BladeFLASK	QFYGEN	09337363001247
		29337363001241
	QFYUKGEN	09337363001278
		29337363001272
	QFYUKSM	09337363001285
		29337363001289
BladeBOX	QBB2Y	09337363001254
		39337363001255
BladeFlask EVO	QBVYGEN	09337363001759
		29337363001753
	QBVYUKGEN	09337363001773
		29337363001777
	QBVYUKSM	09337363001797
		29337363001791