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QLICKSMART®
... and be safe

Declaration of Conformity
(Annex II excl. section 4, Annex V, Annex VII, Directive 93/42/EEC)

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

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

We, the manufacturer, herewith declare that the products
Qlicksmart Single-Use Sterile Scalpel Blade Removers:
BladeSINGLE, BladeCASSETTE, BladeNeedleSYSTEM, BladeCARTRIDGE
GMDN code 46236, Preferred term
meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to Class I according to Annex IX of the Directive 93/42/EEC as amended by Directive 2007/47/EC. It bears the mark CE 0123.

We hereby declare that the above mentioned devices comply with the European Medical Device Directives 93/42/EEC and are designed and manufactured under production quality assurance according to Annex VII of the Directive 93/42/EEC as amended by Directive 2007/47/EC.

Compliance of the designed product with Directive 93/42/EEC as amended by Directive 2007/42/EC has been assessed and certified by the Notified Body:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, D-80339 Munich, Germany

Standards applied include but not limit to the following standards:
EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11137-3:2017, EN 556-1:2001, EN ISO 15223-1:2016, EN ISO 14971:2012, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 14644-1:2015, EN ISO 14644-2:2015, ISO 11737-1:2018, ISO 11737-2:2009, EN 1SO 13485:2016.

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: 25 - Nov - 2019
Brisbane