

EC – DECLARATION OF CONFORMITY

**Medicel AG
Dornierstrasse 11
CH-9423 Altenrhein
Switzerland**

Declares under the sole responsibility that the product(s): **Swiss Bi-Manual I/A Systems
Swiss Quick Switch I/A Systems**

Meet(s) all applicable provisions of the medical device directive and its **93/42/EEC
conversion in national laws**

Classification according to 93/42/EEC Annex IX **Class IIa**

Certified by **MedCert GmbH
Pilatuspool 2
DE – 20355 Hamburg
Germany**

Certified according to **93/42/EEC Annex II**

CE Mark **CE0482**

This document is valid for three years after its date of signature

Altenrhein, November 6th, 2018



Tobias Maier
Chief Operating Officer

Annex A

Swiss Bi-Manual I/A Systems

SBA100A	Swiss Bi-Manual Aspiration 21G Aeroplane	Rev.01
SBA103A	Swiss Bi-Manual Aspiration 21G Aeroplane	Rev.01
SBA104A	Swiss Bi-Manual Aspiration 21G Aeroplane	Rev.01
SBA105A	Swiss Bi-Manual Aspiration 21G Aeroplane	Rev.01
SBA101B	Swiss Bi-Manual Aspiration 23G Bullet Shape	Rev.01
SBA110	Luer Adapter for Asp. Cannulas	Rev.00
SBA106B	Swiss Bi-Manual Aspiration 23G Bullet Shape	Rev.01
SBI120A	Swiss Bi-Manual Irrigation 21G Aeroplane	Rev.01
SBI125A	Swiss Bi-Manual Irrigation 21G Aeroplane	Rev.01
SBI121B	Swiss Bi-Manual Irrigation 23G Bullet Shape	Rev.01
SBI126B	Swiss Bi-Manual Irrigation 23G Bullet Shape	Rev.01
SBI130	Luer Adapter for Irr. Cannulas	Rev.00

Swiss Quick Switch I/A Systems

SQS100	SQS I/A Handpiece	Rev.01
SQS110	I/A Tip straight 1,8mm	Rev.01
SQS115	I/A Tip straight 1,4mm	Rev.00
SQS116	I/A Tip straight 19G with Sleeve	Rev.00
SQS119	I/A Tip 45° angled 19G with Sleeve	Rev.00
SQS120	I/A Tip 45° angled 1,8mm	Rev.01
SQS130	I/A Tip 90° angled 1,8mm	Rev.00
SQS140	I/A Tip curved 1,8mm	Rev.00
SQS145	I/A Tip curved 1,4mm	Rev.00
SQS150	I/A Tip simcoe style 1,8mm	Rev.00
SQS170	I/A Tip binkhorst 1,8mm	Rev.00
SQS180	I/A Tip Luer Adaptor Needle	Rev.00