medicel
SWISS TECHNOLOGY FOR SURGERY

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** **Reference to Annex A**
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	CE 0482

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

Altenrhein, December 27th, 2018

Tobias Maier
Chief Operating Officer

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Annex A – Swiss Bi-Manual I/A Systems

SBS105	**Swiss Bi-Manual I/A System curved / 21G**	**Rev.02**
SBS105RU	**Swiss Bi-Manual I/A System curved / 21G multiple-use**	**Rev.02**
SBS110A	**Swiss Bi-Manual I/A System curved / 21G**	**Rev.02**
SBS110ARU	**Swiss Bi-Manual I/A System curved / 21G multiple-use**	**Rev.02**
SBS123A	**Swiss Bi-Manual I/A System curved / 23G**	**Rev.02**
SBS122A	**Swiss Bi-Manual I/A System curved / 22G**	**Rev.02**
C700B/21	**Swiss Bi-Manual I/A System curved / 21G**	**Rev.00**
SBS310	**Swiss Bi-Manual I/A System curved / 21G**	**Rev.01**
SBS320	**Swiss Bi-Manual I/A System curved / 23G**	**Rev.01**
RIAB21CR	**Swiss Bi-Manual I/A System curved / 21G**	**Rev.00**
RIAB23CR	**Swiss Bi-Manual I/A System curved / 23G**	**Rev.00**
RIAB21CR_C	**Swiss Bi-Manual I/A System curved / 21G**	**Rev.00**
MBSCR21	**Bi-Manual I/A CR21**	**Rev.01**
MBSCR23	**Bi-Manual I/A CR23**	**Rev.01**
1401-2121	**Swiss Bi-Manual I/A System curved / 21G**	**Rev.00**
1401-2123	**Swiss Bi-Manual I/A System curved / 23G**	**Rev.00**