

EC – DECLARATION OF CONFORMITY

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

Declares under the sole responsibility that the product(s):

**Swiss Coaxial 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

CE0482

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

Altenrhein, December 27th, 2018



Tobias Maier
Chief Operating Officer

Annex A – Swiss Mono-Manual I/A Systems

SMS110	Swiss Coaxial I/A System straight / 19G	Rev.00
SMS115	Swiss Coaxial I/A System straight / 20G	Rev.03
SMS120	Swiss Coaxial I/A System angled 45° / 19G	Rev.03
SMS120RU	Swiss Coaxial I/A System angled 45° / 19G multiple-use	Rev.00
SMS125P	Swiss Coaxial I/A System angled 45° / 20G	Rev.03
SMS125PRU	Swiss Coaxial I/A System angled 45° / 20G multiple-use	Rev.03
SMS130	Swiss Coaxial I/A System angled 65° / 19G	Rev.03
SMS135	Swiss Coaxial I/A System angled 65° / 20G	Rev.03
SMS135P	Swiss Coaxial I/A System angled 65° / 20G	Rev.02
SMS135RU	Swiss Coaxial I/A System angled 65° / 20G multiple-use	Rev.00
SMS140	Swiss Coaxial I/A System angled 30° / 19G	Rev.00
SMS145	Swiss Coaxial I/A System angled 30° / 20G	Rev.00
SMS155P	Swiss Coaxial I/A System angled 45° / 21G	Rev.02
SMS160P	Swiss Coaxial I/A System curved / 21G	Rev.02
SMS165	Swiss Coaxial I/A System angled 65° / 21G	Rev.00
SMS165P	Swiss Coaxial I/A System angled 65° / 21G	Rev.02
SMS170P	Swiss Coaxial I/A System angled 45° / 23G	Rev.02
SMS170PRU	Swiss Coaxial I/A System angled 45° / 23G multiple-use	Rev.02
SMS175P	Swiss Coaxial I/A System curved / 23G	Rev.02
SMS175PRU	Swiss Coaxial I/A System curved / 23G multiple-use	Rev.00
SMS180P	Swiss Coaxial I/A System curved / 25G	Rev.02
SMS210	Femto I/A Handpieces 30°/20G	Rev.02
SMS230	Femto I/A Handpieces 30°/21G	Rev.02
C650/19	Coaxial I/A System angled 65° / 19G	Rev.01
C650/20	Coaxial I/A System angled 65° / 20G	Rev.02
C660P/20	Coaxial I/A System angled 65° / 20G	Rev.02
C670/21	Coaxial I/A System angled 65° / 21G	Rev.01
SMS325P	Swiss Coaxial I/A System angled 45° / 20G	Rev.01
SMS335	Swiss Coaxial I/A System angled 65° / 20G	Rev.01
SMS355P	Swiss Coaxial I/A System angled 45° / 21G	Rev.01
SMS370P	Swiss Coaxial I/A System angled 45° / 23G	Rev.01
SMS390S	Swiss Coaxial I/A System Soft Tip angled 45° / 21G	Rev.00
SMS410	Femto I/A Handpieces 30°/20G	Rev.00

SMS430	Femto I/A Handpieces 30°/21G	Rev.00
MCS4520P	Coaxial I/A 4520P	Rev.01
MCS6520T	Coaxial I/A 6520T	Rev.01
MCS4521P	Coaxial I/A 4521P	Rev.01
MCS4523P	Coaxial I/A4523P	Rev.01
MCS4521ST	Coaxial I/A 4521ST	Rev.00
RIA20ST_C	Swiss Coaxial I/A System straight / 20G	Rev.00
RIA1945T_C	Swiss Coaxial I/A System angled 45° / 19G	Rev.00
RIA2045P_C	Swiss Coaxial I/A System angled 45° / 20G	Rev.00
RIA1965T_C	Swiss Coaxial I/A System angled 65° / 19G	Rev.00
RIA2065T_C	Swiss Coaxial I/A System angled 65° / 20G	Rev.00
RIA2145P_C	Swiss Coaxial I/A System angled 45° / 21G	Rev.00
RIA21CRP_C	Swiss Coaxial I/A System curved/ 21G	Rev.00
RIA2345P_C	Swiss Coaxial I/A System angled 45° / 23G	Rev.00
RIA23CRP_C	Swiss Coaxial I/A System curved / 23G	Rev.00
RIA25CRP_C	Swiss Coaxial I/A System curved / 25G	Rev.00
RIA2030B_C	Femto I/A Handpieces 30°/20G	Rev.00
RIA2130B_C	Femto I/A Handpieces 30°/21G	Rev.00
RIA2045P	Swiss Coaxial I/A System angled 45° / 20G	Rev.00
RIA2065T	Swiss Coaxial I/A System angled 65° / 20G	Rev.00
RIA2145P	Swiss Coaxial I/A System angled 45° / 21G	Rev.00
RIA2345P	Swiss Coaxial I/A System angled 45° / 23G	Rev.00
RIA2145S	Swiss Coaxial I/A System Soft Tip angled 45° / 21G	Rev.00
1401-2220	Swiss Coaxial I/A System angled 45° / 20G	Rev.00
1401-2230	Swiss Coaxial I/A System angled 65° / 20G	Rev.00
1401-2221	Swiss Coaxial I/A System angled 45° / 21G	Rev.00
1401-2223	Swiss Coaxial I/A System angled 45° / 23G	Rev.00
1401-2243	Swiss Coaxial I/A System Soft Tip angled 45° / 21G	Rev.00