

SQS as a conformity assessment body identification number 1250 herewith certifies the organisation

Swiss Medical Instruments AG
Roosstrasse 10A
8832 Wollerau
Switzerland

the use of a quality assurance system in its design, development, manufacturing and distribution which fulfills the requirements set out in:

ANNEX II

Directive 93/42/EEC (without section 4)

This approval is based on the report dated March 4, 2020.

The scope of validity covers the products

**Hip-Screw, Capsa-Knife and drill class IIa
for use in distraction of the hip joint with the HIP-FIX system
Sterile Shaver Blades and Burrs**

The following CE label can be applied to these products mentioned in the Appendix of this certificate

CE 1250

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the Directive 93/42/EEC.

Reg. no. 42362

Validity 06.03.2020–25.05.2024
Issue 06.03.2020

Approved Medical Responsible
06.03.2020



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



ANNEX II

Directive 93/42/EEC (without section 4)

This Appendix is valid only in connection with the following certificate:

Registration Number 42362

Validity from March 6, 2020 up to and including May 25, 2024

This approval includes the following Medical Device/s:

Klasse IIa

300.001 Hip-Screw 6mm
 300.010 Hip-Screw 6.5mm
 300.005 Capsa-Knife
 300.033 Drill Ø 4.7mm
 300.156 Drill Ø 4.9mm
 201.006 Oval Burr Ø 4.2
 202.006 Oval Burr Ø 4.2
 203.006 Oval Burr Ø 4.2
 201.004 Oval Burr Ø 4.2 for frontal use
 202.004 Oval Burr Ø 4.2 for frontal use
 203.004 Oval Burr Ø 4.2 for frontal use
 201.007 Oval Burr Ø 5.5
 202.007 Oval Burr Ø 5.5
 203.007 Oval Burr Ø 5.5
 201.005 Oval Burr Ø 5.5 for frontal use
 202.005 Oval Burr Ø 5.5 for frontal use
 203.005 Oval Burr Ø 5.5 for frontal use
 201.008 Oval Burr Ø 6.5 for frontal use
 202.008 Oval Burr Ø 6.5 for frontal use
 203.008 Oval Burr Ø 6.5 for frontal use
 201.009 Round Burr Ø 4.2
 202.009 Round Burr Ø 4.2
 203.009 Round Burr Ø 4.2
 201.012 Round Burr Ø 5.5
 202.012 Round Burr Ø 5.5
 203.012 Round Burr Ø 5.5
 201.011 Round Burr Ø 5.5 for frontal use
 202.011 Round Burr Ø 5.5 for frontal use
 203.011 Round Burr Ø 5.5 for frontal use
 201.013 Tapered Burr Ø 5.5
 202.013 Tapered Burr Ø 5.5
 203.013 Tapered Burr Ø 5.5
 201.014 Aggressive Full-Radius Ø 4.2 Curved
 202.014 Aggressive Full-Radius Ø 4.2 Curved
 203.014 Aggressive Full-Radius Ø 4.2 Curved
 201.015 Aggressive Full-Radius Resector Ø 3.4
 202.015 Aggressive Full-Radius Resector Ø 3.4
 203.015 Aggressive Full-Radius Resector Ø 3.4
 201.016 Aggressive Full-Radius Resector Ø 4.2
 202.016 Aggressive Full-Radius Resector Ø 4.2
 203.016 Aggressive Full-Radius Resector Ø 4.2
 201.017 Aggressive Full-Radius Resector Ø 5.5
 202.017 Aggressive Full-Radius Resector Ø 5.5
 203.017 Aggressive Full-Radius Resector Ø 5.5
 201.018 Cutter Ø 4.2
 202.018 Cutter Ø 4.2
 203.018 Cutter Ø 4.2



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This approval includes the following Medical Device/s:

201.001	Cutting-Blade Ø 3.4
202.001	Cutting-Blade Ø 3.4
203.001	Cutting-Blade Ø 3.4
201.019	Cutting-Blade Ø 3.4 Bendable
202.019	Cutting-Blade Ø 3.4 Bendable
203.019	Cutting-Blade Ø 3.4 Bendable
201.002	Cutting-Blade Ø 4.2
202.002	Cutting-Blade Ø 4.2
203.002	Cutting-Blade Ø 4.2
201.020	Cutting-Blade Ø 4.2 Bendable
202.020	Cutting-Blade Ø 4.2 Bendable
203.020	Cutting-Blade Ø 4.2 Bendable
201.010	Cutting-Blade Ø 4.2 Curved
202.010	Cutting-Blade Ø 4.2 Curved
203.010	Cutting-Blade Ø 4.2 Curved
201.003	Cutting-Blade Ø 5.5
202.003	Cutting-Blade Ø 5.5
203.003	Cutting-Blade Ø 5.5
201.021	Double Aggressive Full-Radius Ø 4.2
202.021	Double Aggressive Full-Radius Ø 4.2
203.021	Double Aggressive Full-Radius Ø 4.2
201.022	Double Aggressive Full-Radius Ø 5.5
202.022	Double Aggressive Full-Radius Ø 5.5
203.022	Double Aggressive Full-Radius Ø 5.5
201.023	End Cutter Ø 4.2
202.023	End Cutter Ø 4.2
203.023	End Cutter Ø 4.2
201.024	End Cutter Ø 5.5
202.024	End Cutter Ø 5.5
203.024	End Cutter Ø 5.5
201.025	Full Radius Resector Ø 3.4
202.025	Full Radius Resector Ø 3.4
203.025	Full Radius Resector Ø 3.4
201.026	Full Radius Resector Ø 4.2
202.026	Full Radius Resector Ø 4.2
203.026	Full Radius Resector Ø 4.2
201.027	Full Radius Resector Ø 4.2 Curved
202.027	Full Radius Resector Ø 4.2 Curved
203.027	Full Radius Resector Ø 4.2 Curved
201.028	Full Radius Resector Ø 5.5
202.028	Full Radius Resector Ø 5.5
203.028	Full Radius Resector Ø 5.5
201.029	Meniscus Cutter Ø 3.4
202.029	Meniscus Cutter Ø 3.4
203.029	Meniscus Cutter Ø 3.4
201.030	Meniscus Cutter Ø 4.2
202.030	Meniscus Cutter Ø 4.2
203.030	Meniscus Cutter Ø 4.2
201.031	Meniscus Cutter Ø 5.5
202.031	Meniscus Cutter Ø 5.5
203.031	Meniscus Cutter Ø 5.5
204.001	Cutting-Blade Ø 3.5
204.002	Cutting-Blade Ø 4.3
204.003	Cutting-Blade Ø 5.6
204.004	Oval Burr Ø 4.2 for frontal use
204.005	Oval Burr Ø 5.5 for frontal use
204.006	Oval Burr Ø 4.3
204.007	Oval Burr Ø 5.6
204.008	Oval Burr Ø 6.5 for frontal use



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This approval includes the following Medical Device/s:

- 204.009 Round Burr Ø 4.3
- 204.010 Cutting-Blade Ø 4.2 Curved
- 204.011 Round Burr Ø 5.5 for frontal use
- 204.012 Rund Burr Ø 5.6
- 204.013 Tapered Burr Ø 5.6
- 204.014 Aggressive Full-Radius Ø 4.2 Curved
- 204.015 Aggressive Full-Radius Resector Ø 3.5
- 204.016 Aggressive Full-Radius Resector Ø 4.3
- 204.017 Aggressive Full-Radius Resector Ø 5.6
- 204.018 Cutter Ø 4.3
- 204.019 Cutting-Blade Ø 3.4 Bedable
- 204.020 Cutting-Blade Ø 4.2 Bendable
- 204.021 Double Aggressive Full-Radius Ø 4.3
- 204.022 Double Aggressive Full-Radius Ø 5.6
- 204.023 End Cutter Ø 4.3
- 204.024 End Cutter Ø 5.6
- 204.025 Full Radius Resector Ø 3.5
- 204.026 Full Radius Resector Ø 4.3
- 204.027 Full Radius Resector Ø 4.2 Curved
- 204.028 Full Radius Resector Ø 5.6
- 204.029 Meniscus Cutter Ø 3.5
- 204.030 Meniscus Cutter Ø 4.3
- 204.031 Meniscus Cutter Ø 5.5

Appendix Issue: 06. March 2020

