

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

Bonebridge AG
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6300 Zug
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 December 4, 2020.

The scope of validity covers the products

**Osteosynthesis implants and
Orthopaedic instruments**

The following CE label can be applied to the 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.3 of the Directive 93/42/EEC.

Reg. no. 46346

Validity 01.02.2021 – 25.05.2024
Issue 01.02.2021

Approved Medical Responsible
01.02.2021



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 46346

Validity from February 1, 2021 up to and including May 25, 2024

This approval includes the following Medical Devices:

Class IIa

Reusable surgical instruments:

- Power Tool TL Attachment 3.5mm
- Exchangeable Bit 3.5mm Short
- Exchangeable Bit 3.5mm Long
- Drill Bit Ø 2.8mm x 120mm
- Drill Bit Ø 2.8mm x 220mm
- K-Wire Ø 1.8mm x 250mm
- K-Wire 1.4mm x 150mm
- Drill Bit 1.9mm
- CASCELLA Trial Implant 7H/9H
- SALGINA Trial Implant

Class IIb

CASCELLA 3.5mm Superior Clavicle System:

- CASCELLA 3.5mm Superior Clavicle Plate, 7 Hole, Left
- CASCELLA 3.5mm Superior Clavicle Plate, 7 Hole, Right
- CASCELLA 3.5mm Superior Clavicle Plate, 9 Hole, Left
- CASCELLA 3.5mm Superior Clavicle Plate, 9 Hole, Right
- CASCELLA 3.5mm Superior Clavicle Plate, Lateral, 9 Hole Left
- CASCELLA 3.5mm Superior Clavicle Plate, Lateral, 9 Hole Right
- CASCELLA 3.5mm Superior Clavicle Plate, Lateral, 12 Hole Left
- CASCELLA 3.5mm Superior Clavicle Plate, Lateral, 12 Hole Right
- Cortical Screw Ø 3.5mm; Length 10–30mm
- Variable Angle Locking Screw Ø 3.5mm; Length 10–30mm

Class IIb

SALGINA 2.5mm Volar Distal Radius System:

- SALGINA 2.5mm Volar Distal Radius Plate Wide Right
- SALGINA 2.5mm Volar Distal Radius Plate Wide Left
- SALGINA 2.5mm Volar Distal Radius Plate Small Right
- SALGINA 2.5mm Volar Distal Radius Plate Small Left
- Cortical Screw Ø 2.5mm; Length 10–60mm
- Variable Angle Locking Screw Ø 2.5mm; Length 10–60mm

Class Im:

- Depth Gauge 3.5mm
- Depth Gauge 2.5mm

Appendix Issue: February 1, 2021

