

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

Bonebridge AG
Bahnhofstrasse 11
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 August 22, 2020.

The scope of validity covers the products

**Osteosynthesis implants and
Orthopaedic instruments**

The following CE label can be applied to the product 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. 46104

Validity 19. 11. 2020 – 25. 05. 2024
Issue 19. 11. 2020

Approved Medical Responsible
19. 11. 2020



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



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Swiss Association for Quality
and Management Systems (SQS)
Bernstrasse 103, 3052 Zollikofen, Switzerland



ANNEX II

Directive 93/42/EEC (without section 4)

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

Registration Number 46104

Validity from November 19, 2020 up to and including May 25, 2024

This approval includes the following Medical Device/s:

Instruments Class IIa:

Drill Bit Ø3.5mm x 220mm

Drill Bit Ø3.5mm x 110mm

TAMINA Implants Class IIb:

TAMINA 3.5mm Proximal Humerus Plate, 3 Hole, Left

TAMINA 3.5mm Proximal Humerus Plate, 3 Hole, Right

TAMINA 3.5mm Proximal Humerus Plate, 5 Hole, Left

TAMINA 3.5mm Proximal Humerus Plate, 5 Hole, Right

TAMINA 3.5mm Proximal Humerus Plate, TF, 3 Hole, Left

TAMINA 3.5mm Proximal Humerus Plate, TF, 3 Hole, Right

TAMINA 3.5mm Proximal Humerus Plate, TF, 5 Hole, Left

TAMINA 3.5mm Proximal Humerus Plate, TF, 5 Hole, Right

Variable Angle Locking Screw Ø3.5mm; Lengths 32–60mm

TRIFT Implants Class IIb:

TRIFT 3.5mm 1/3 Tubular Plate, 3 Hole

TRIFT 3.5mm 1/3 Tubular Plate, 5 Hole

TRIFT 3.5mm 1/3 Tubular Plate, 7 Hole

TRIFT 3.5mm 1/3 Tubular Plate, 9 Hole

TRIFT 3.5mm 1/3 Tubular Plate, 11 Hole

TRIFT 3.5mm 1/3 Tubular Plate, 13 Hole

Cortical Screw Ø3.5mm; Lengths 32–60mm

Appendix Issue: November 19, 2020



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