

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 March 19, 2021.

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. 46481

Validity 08.04.2021–25.05.2024
Issue 08.04.2021

Approved Medical Responsible
08.04.2021



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



sqs.ch

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



Swiss Made



ANNEX II

Directive 93/42/EEC (without section 4)

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

Registration Number 46481

Validity from April 8, 2021 up to and including May 25, 2024

This approval includes the following Medical Device/s:

Class IIb:

DALVAZZA 2.5mm Distal Ulna System

Implant:

DALVAZZA 2.5 mm Distal Ulna Plate

Class IIb:

POYA 3.5 Lateral Proximal Tibia System

Implants:

POYA 3.5mm Lateral Proximal Tibia Plate, Left

POYA 3.5mm Lateral Proximal Tibia Plate, Right

Variable Angle Locking Screw ø3.5mm L65mm

Variable Angle Locking Screw ø3.5mm L70mm

Variable Angle Locking Screw ø3.5mm L75mm

Variable Angle Locking Screw ø3.5mm L80mm

Variable Angle Locking Screw ø3.5mm L85mm

Variable Angle Locking Screw ø3.5mm L90mm

Cortical Screw ø3.5mm L65mm

Cortical Screw ø3.5mm L70mm

Cortical Screw ø3.5mm L75mm

Cortical Screw ø3.5mm L80mm

Cortical Screw ø3.5mm L85mm

Cortical Screw ø3.5mm L90mm

Cortical Screw ø3.5mm L95mm

Cortical Screw ø3.5mm L100mm

Class Im Instruments:

Depth Gauge 3.5mm L10 – L100

Class IIb:

POYA 3.5mm Posteromedial Tibia System

Implants:

POYA 3.5mm Posteromedial Tibia Plate, Left

POYA 3.5mm Posteromedial Tibia Plate, Right

Variable Angle Locking Screw ø3.5mm L65mm

Variable Angle Locking Screw ø3.5mm L70mm

Variable Angle Locking Screw ø3.5mm L75mm

Variable Angle Locking Screw ø3.5mm L80mm

Variable Angle Locking Screw ø3.5mm L85mm

Variable Angle Locking Screw ø3.5mm L90mm

Cortical Screw ø3.5mm L65mm

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Class Im Instruments:

Depth Gauge 3.5mm L10 – L100

Appendix Issue: April 8, 2021

