



Certificate

SQS herewith certifies that the company named below has a management system which meets the requirements of the normative base specified below.

Gerraspine AG
CH-9016 St. Gallen

Certified area

Entire Company

Field of activity

**Design, development, manufacture and sales
of orthopedic implants and instruments**

Normative base

**ISO 13485:2003 Medical devices –
Quality Management System**

Swiss Association for Quality and
Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: April 10, 2010

This SQS Certificate is valid up to
and including April 9, 2013
Scope numbers 17, 18, 19
Registration number 33631

X. Edelmann, President SQS

T. Zahner, Managing Director SQS



SCESm 001
CE 1250



Swiss Made





EC-Certificate

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

Gerraspine AG
CH-9016 St. Gallen

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

ANNEX II.3

Directive 93/42/EEC

This approval is based on the result of the audit documented in the report dated February 15, 2010.

The scope of validity covers the products

FENIX® FACET IMLANTS:
FENIX®-Superior Facet Implants
FENIX®-Inferior Facet Implants
FENIX®-Locking Screws

The following CE label can be applied to these products

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.

Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: April 10, 2010

This SQS Certificate is valid up to and including April 9, 2013
Registration number 33632
Approved Medical Responsible:
February 15, 2010

T. Zahner, Managing Director SQS

K. Schulze, Medical Responsible



SCESm 001
CE 1250



Swiss Made

