



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
Rorschacherstrasse 292
CH-9016 St. Gallen

Certified area

Entire Company

Field of activity

Development, production and sales of orthopedic implants and instruments

Normative base

ISO 13485:2003

**Medical device manufacturers –
Quality management system**

Swiss Association for Quality and
Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: April 10, 2007

This SQS Certificate is valid up to
and including April 9, 2010
Scope numbers 17, 18, 19
Registration number 33631

X. Edelmann, President SQS

T. Zahner, Managing Director SQS



SCESm 001, 002
CE 1250



Swiss Made





EC-Certificate

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

Gerraspine AG
Rorschacherstrasse 292
CH-9016 St. Gallen

the use of a quality assurance system in its design, manufacture, final inspection and distribution which fulfills the requirements set out below

ANNEX II.3

EC-Directive 93/42/EEC

This approval is based on the result of the audit documented in the report dated March 23, 2007.

The scope of validity covers the products

FENIX™ FACET IMPLANTS

The following CE label can be applied to these products

CE 1250

A condition for the validity of the certificate is a regular examination in accordance with Annex II.5.

Swiss Association for Quality and
Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: April 10, 2007

This SQS Certificate is valid up to
and including April 9, 2010
Registration number 33632
Approved PM Medical: April 10, 2007

T. Zahner, Managing Director SQS

Medical Responsible



SCES 001, 002,
CE 1250



Swiss Made

