



Certificate

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



Leica Microsystems (Schweiz) AG
Max Schmidheiny-Strasse 201
CH-9435 Heerbrugg

Certified area

Surgical Division

Field of activity

**Design, development and manufacture
of Surgical Microscopes, Surgical Microscope
Systems including accessories**

Normative bases

ISO 9001:2008 **Quality Management System**
ISO 14001:2004 **Environmental Management System**
ISO 13485:2003 **Medical devices –
Quality Management System**

Swiss Association for Quality and
Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: June 5, 2010

This SQS Certificate is valid up to
and including June 4, 2013
Scope number 19
Registration number 12667

X. Edelman, 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

Leica Microsystems (Schweiz) AG
Max Schmidheiny-Strasse 201
CH-9435 Heerbrugg

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

ANNEX II.3

EC-Directive 93/42/EEC

This approval is based on the result of the audit documented in the report dated May 11, 2010.

The scope of validity covers the product

Surgical Microscope Accessory
Leica FL 800

The following CE label can be applied to this product

CE 1250

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the EC-Directive 93/42/EEC.

Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: June 5, 2010

This SQS Certificate is valid up to and including June 4, 2013
Registration number 34669
Approved PM Medical: May 20, 2010

T. Zahner, Managing Director SQS

W. Hostettler, Medical Responsible

