



Certificate

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



Regen LAB
CH-1146 Mollens VD

Certified area

Whole Company

Field of activity

Development and Marketing of Medical Devices

Normative bases

ISO 9001:2000

ISO 13485:2003

Quality management system

**Medical device manufacturers –
Quality management system**

Swiss Association for Quality and
Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: December 23, 2006

This SQS Certificate is valid up to
and including December 22, 2009
Scope number 19
Registration number 23788

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



Regen LAB
CH-1146 Mollens VD

the use of a quality assurance system in its design, 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 January 30, 2007.

The scope of validity covers the products

Versions of the RegenKit, type IIb : RegenKit-ATS – A / RegenKit-ATS – AZ / RegenKit-Extracell / Regen ACR – C / Regen BCT – D and their accessories of type II b as well: Regen PRP SP / Regen THT SP / Regen BCT SP (SP = Spare Part)

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: December 23, 2006

This SQS Certificate is valid up to and including December 22, 2009
Scope number 19
Registration number 33500

T. Zahner, Managing Director SQS

K. Schulze, Medical Responsible



SCES 001, 002,
CE 1250



Swiss Made

