



Certificate

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



Primequal SA
CH-1207 Genève

Certified area

The whole company

Field of activity

**Design, manufacturing and sales of medical
and dental devices**

Normative bases

ISO 9001:2008 **Quality 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: September 25, 2009

This SQS Certificate is valid up to
and including September 24, 2012
Scope numbers 19
Registration number 32792

X. Edelmann, President SQS

T. Zahner, Managing Director SQS



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EC-Certificate

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



Primequal SA CH-1207 Genève

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

ANNEX V.3

Directive 93/42/EEC

This approval is based on the result of the audit documented in the report dated August 25, 2009

The scope of validity covers the products

Sterile injectors

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 V.4 of the Directive 93/42/EEC.

Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: September 25, 2009

This SQS Certificate is valid up to and including September 24, 2012
Registration number 36424
Approved Medical Responsible:
October 15, 2009

T. Zahner, Managing Director SQS

K. Schulze, Medical Responsible



SCESm 001
CE 1250



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