



Certificate

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

Max Stäubli AG
8810 Horgen
Switzerland

Certified area

Whole Company

Field of activity

Medical suction equipment, Respiratory therapy equipment, Urological catheter valves, Dispensing devices for medical gases and vacuum

Standard

EN ISO 13485:2012 Medical devices – Quality Management System

Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: December 1, 2013

This SQS Certificate is valid up to and including November 30, 2016
Scope number 19
Registration number 22610

X. Edelmann

X. Edelmann, President SQS

R. Glauser

R. Glauser, CEO SQS



Trusted Cert



SCESm 001



Swiss Made





EC-Certificate

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

Max Stäubli AG
8810 Horgen
Switzerland

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

ANNEX V

Directive 93/42/EEC

This approval is based on the result of the audit documented in the report dated November 27, 2013.

The scope of validity covers the products

Drainage, suction pumps and their accessories

The following CE label can be applied to the products mentioned in the Appendix of this certificate

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: December 1, 2013

This SQS Certificate is valid up to and including November 30, 2016
Registration number 33295
Approved Medical Responsible:
November 27, 2013


R. Glauser, CEO SQS


U. Decurtins, Medical Responsible



Trusted Cert



SCESm 001
CE 1250

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Partner of


ANNEX V

Directive 93/42/EEC

This Appendix is valid only in connection with the following certificate:

Registration Number 33295

Validity from December 1, 2013 up to and including November 30, 2016

This approval includes the following Medical Device/s:

Class I s

Urological catheter valves KV100 / KV 100 EH / KV 200 EH / KP 200 / KV 100 KP / KV 200 EHKP

Class IIa

Drainage pumps AUES

Drainage pumps U

Drainage pumps S

Drainage pumps ES

Universal suction pumps

Univac suction pumps

Minivac suction pumps

Aeroboy inhalation device

Suction breaker AU ZA

Suction breaker AU ES ZA

Tubing systems including plug nipples

Vacuum regulators for central supply systems

Appendix issue date: November 27, 2013



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SCESm 001
CE 1250



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