



Certificate

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



Mecaplast SA
Rte du Villard 31
1652 Botterens
Switzerland

Certified area

Whole company

Field of activity

Engineering and conception
Moulds manufacture
Plastic injection
Assembly, cleaning and packaging of components
and sterile and non sterile medical devices

Standard

EN ISO 13485:2012 **Medical devices – Quality Management System**

Scope(s) 14, 19

Validity 11.10.2016–28.02.2019
Issue 11.10.2016

Reg. no. 30461

X. Edelmann, President SQS

R. Glauser, CEO SQS



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Swiss Association for Quality and
Management Systems SQS
Bernstrasse 103, 3052 Zollikofen, Switzerland





EC-Certificate

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

Mecaplast SA
Rte du Villard 31
1652 Botterens
Switzerland

the use of a quality assurance system in its design, development, 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 October 7, 2016.

The scope of validity covers the product

Bur Guard – sterile medical device of class I

The following CE label can be applied to these products mentioned in 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.

Scope(s) 14, 19

Validity 11.10.2016–28.02.2019
Issue 11.10.2016

Reg. no. 37623
Approved Medical Responsible:
08.10.2016

X. Edelmann, President SQS

K. Schulze, Medical Responsible



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