



Attestation

The SQS herewith attests that the organisation named below has a management system that meets the requirements of the normative base mentioned.



CCL Label AG
Weststrasse 12
5426 Lengnau AG
Switzerland

Certified sites according to appendix

Scope

Lengnau: Development, production and distribution of printed and unprinted self-adhesive labels in flexographic, screen and digital printing processes made of paper and plastic films for the pharmaceutical industry using self-adhesive raw materials or selfcoating and printing of adhesives in the secondary packaging sector.

Kleindöttingen: Production of cardboard packaging for the pharmaceutical industry in the secondary packaging sector.

Normative base

ISO 15378:2017

Primary Packaging Materials for Medicinal Products

Particular requirements for the application of ISO 9001:2015, with reference to Good Manufacturing Practice (GMP)

Compliance with the requirements of ISO 15378:2017 have been applied mutatis mutandis to the secondary packaging industry and the following can be confirmed:

- Compliance with Good Manufacturing Practice (GMP)
- Established risk management across all relevant areas
- Focus on product safety / patient safety
- Appropriate infrastructure established
- Maintenance and cleaning activities according to GMP
- Established GMP training concept
- Compliance with additional measures for externally provided products and services
- Verification, qualification and validation according to GMP
- Avoidance of contamination
- Compliance with the change process
- Compliance with additional requirements for handling deviations

Reg. no. H47608
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Swiss Association for Quality and Management Systems (SQS)
Bernstrasse 103, 3052 Zollikofen, Switzerland





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Weststrasse 12
5426 Lengnau AG
Switzerland

Central Function	Scope	Norm / Revision	Reg. no.	Validity
CCL Label AG Weststrasse 12 5426 Lengnau AG Switzerland	Lengnau: Development, production and distribution of printed and unprinted self-adhesive labels in flexographic, screen and digital printing processes made of paper and plastic films for the pharmaceutical industry using self-adhesive raw materials or self-coating and printing of adhesives in the secondary packaging sector. Kleindöttingen: Production of cardboard packaging for the pharmaceutical industry in the secondary packaging sector.	ISO 15378:2017	H47608	19.11.2024 18.11.2027

Locations	Scope	Norm / Revision	Reg. no.	Validity
CCL Speciality Cartons Gewerbestrasse 113.1 5314 Kleindöttingen Switzerland	Lengnau: Development, production and distribution of printed and unprinted self-adhesive labels in flexographic, screen and digital printing processes made of paper and plastic films for the pharmaceutical industry using self-adhesive raw materials or self-coating and printing of adhesives in the secondary packaging sector. Kleindöttingen: Production of cardboard packaging for the pharmaceutical industry in the secondary packaging sector.	ISO 15378:2017	H47608	19.11.2024 18.11.2027

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The validity of this appendix depends on the validity of the main certificate.


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