



Attestation

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



LANGE AG Urdorf
Steinackerstrasse 31
8902 Urdorf
Switzerland

Scope

Secondary packaging
Manufacturing and distribution of labels and security products for the pharmaceutical domain

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

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Page 1 of 1

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