

Attestation

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

Druckerei Bloch AG Talstrasse 40 4144 Arlesheim Switzerland

Further sites according to appendix

Scope

Production of offset-printed and unprinted solid board folding cartons for use as secondary packaging in the pharmaceutical industry

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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5531_2/Oktober2021/Version 1.0

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Appendix of main attestation H60452

Druckerei Bloch AG Talstrasse 40 4144 Arlesheim Switzerland

Central Function	Scope	Norm / Revision	Reg. no.	Validity
Druckerei Bloch AG Talstrasse 40 4144 Arlesheim Switzerland	Production of offset-printed and unprinted solid board folding cartons for use as secondary packaging in the pharmaceutical industry	ISO 15378:2017 nicht akkreditiert	H60452	02.10.2020 01.10.2023
Locations	Scope	Norm / Revision	Reg. no.	Validity
Gantenbein AG Offsetdruck und Kartonage Talstrasse 40 4144 Arlesheim Switzerland	Production of offset-printed and unprinted solid board folding cartons for use as secondary packaging in the pharmaceutical industry	ISO 15378:2017 nicht akkreditiert	H60452	02.10.2020 01.10.2023
Druckerei Dürrenberger AG Talstrasse 40 4144 Arlesheim Switzerland	Production of offset-printed and unprinted solid board folding cartons for use as secondary packaging in the pharmaceutical industry	ISO 15378:2017 nicht akkreditiert	H60452	02.10.2020 01.10.2023
Kurt Fankhauser AG Talstrasse 40 4144 Arlesheim Switzerland	Production of offset-printed and unprinted solid board folding cartons for use as secondary packaging in the pharmaceutical industry	ISO 15378:2017 nicht akkreditiert	H60452	02.10.2020 01.10.2023
Fleury Druck GmbH Talstrasse 40 4144 Arlesheim Switzerland	Production of offset-printed and unprinted solid board folding cartons for use as secondary packaging in the pharmaceutical industry	ISO 15378:2017 nicht akkreditiert	H60452	02.10.2020 01.10.2023

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