



Attestation

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



Birkhäuser+GBC AG
Römerstrasse 54
4153 Reinach BL
Switzerland

Scope

Manufacturing of printed (offset, flexo, screen and digital printing) and unprinted folding boxes, pouches, package inserts and self-adhesive labels made of multilayer composites (paper, PE, PP, PET) for use 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

Reg. no. 38022
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Validity 01.07.2020 – 30.06.2023
Issue 28.02.2022


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