



Attestation

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

**Kroha GmbH
Im Hasenwinkel 5
39179 Barleben
Germany**

Scope

Production of package inserts for 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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