

Attestation

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



Körber Pharma Packaging Materials AG Gewerbestrasse 11 4123 Allschwil Switzerland

Further sites according to appendix

Scope

Development and production of printed and unprinted cardboard packaging. Trade in package inserts.

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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Swiss Association for Quality and Management Systems (SQS) Bernstrasse 103, 3052 Zollikofen, Switzerland





Appendix of main attestation H46968



Körber Pharma Packaging Materials AG Gewerbestrasse 11 4123 Allschwil Switzerland

Central Function	Scope	Norm / Revision	Reg. no.	Validity
Körber Pharma Packaging Materials AG Gewerbestrasse 11 4123 Allschwil Switzerland	Development and production of printed and unprinted cardboard packaging. Trade in package inserts.	ISO 15378:2017	H46968	25.05.2022 24.05.2025
Locations	Scope	Norm / Revision	Reg. no.	Validity
Körber Pharma Packaging Materials s.r.o. Zemská 230 33701 Ejpovice Czech Republic	Development and production of printed and unprinted cardboard packaging. Trade in package inserts.	ISO 15378:2017	H46968	25.05.2022 24.05.2025

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