

Medical Packaging Paper

Fact Books Overview

BillerudKorsnäs Medical Paper Fact Books are designed to support the validation of SteriKraft® papers by medical device manufacturers. The Fact Books can be supplied to the device manufacturer following initial screening and selection of candidate materials; they are not designed to be a tool to facilitate the screening process.

The information contained within the Fact Books is divided into four key parts:

GENERAL INFORMATION

This is high-level information that applies to the production of all SteriKraft® medical packaging papers

- a. Information concerning BillerudKorsnäs in general
- b. High level production information
- c. Certifications
- d. Sampling procedures
- e. Test methods

PRODUCT SPECIFIC INFORMATION

Detailed information regarding the grade in question

- a. Intended end uses
- b. Raw materials
- c. Compliance with ISO 11607 1 and EN 868
- d. Shelf Life & Storage recommendations
- e. Traceability
- f. Cleanliness
- g. Bioburden
- h. Microbial barrier properties
- i. Shelf life and stability
- j. Biocompatibility
- k. Heavy metals statement
- I. Notice of change statement
- m. Environmental information

APPLICATION INFORMATION

This section contains information demonstrating fitness of the paper for typical medical device packaging applications. The information in this section does not constitute a guarantee of performance for a specific application

- a. Compatibility with sealing process
- b. Compatibility with sterilisation process
- c. Compatibility with variable data coding equipment

4 APPENDICES

Additional useful data

- a. Technical data sheet
- b. Paper testing information

Fact Books are available on request for commercially available grades.

Please contact your BillerudKorsnäs Sales Team for further information.

