



## CleanFlex® barrier bags

Ensuring that moisture and oxygen are locked out: our CleanFlex® barrier bags stand out thanks to their high-performance water vapor and oxygen barrier, which reliably protects your sensitive and high-purity products. Light is also unable to penetrate into the interior of the packaging.

We manufacture CleanFlex® barrier bags, e.g., in the form of three-side-sealed bags using aluminum or sterilizable, transparent laminates. We custom-design our high-barrier packaging specifically for your application.

### CleanFlex® barrier bags – size range

Type	External width	External length
Minimum	100 mm	110 mm
Maximum	1100 mm	1500 mm

The indicated size range is intended as a guideline.  
Each design has to be checked individually as regards feasibility.

### Material options

- Aluminum laminates (e.g., PET / ALU / PE or PE / ALU / PE)
- Transparent compound (e.g. with PA or EVOH)
- Other film compositions and laminate structures (on request)

### Full traceability

- IR spectrum as proof of material origin
- Certificate of analysis for every production run
- Optional lot number embossing on all bags
- Full labeling of bundles and pallets
- Documentation of entire process

### Consistency of supply policy

- Announcement of raw material changes 2 years prior to implementation
- Strict change control procedures for process changes
- Call-off orders and warehousing as options for contracted business



## Regulatory compliance\*

- Regulation (EU) 10 / 2011 (most recent edition) – food-approved
  - Compliant to FDA 21 CFR
  - 94 / 62 / EC and CONEG – heavy metal declaration
  - EMA 410 / 01 regulation – BSE / TSE statement
- \* After ordering, official certificates / statements will be issued based on the individual material.



## Certification and quality assurance

- IR spectrum of product contact layer
- Dimensions and thickness
- Seal strength
- ISO 9001: 2015
- ISO 15378 : 2017



## Laboratory options

- Additional integrity testing
- Additional age testing
- Additional material testing
- Additional analytical testing



## Long-term stability analysis

- No change in physical properties (5 years)



## Sterilization options

- Suitable for gamma irradiation
- Pre-irradiation can be arranged by Bischof+Klein
- Certificate of irradiation can be provided



## Clean room production

- Particle and biological monitoring in place
- Qualification as per DIN ISO 14644-1 class 5, at rest:
  - Extrusion of film
  - Cleaning of laminate
  - Conversion
  - Bundling and packing



## Tailor-made

- Customized printing
- USP- and EP-compliant product contact layer on request
- Indicator labels for sterilization options

The client is responsible for the suitability of the products for its applications.  
The property values shown are based on a limited number of tests and therefore should not be construed as product specifications.

