



CleanFlex® continuous liner system (cls)

CLS are a simple and effective solution for operator safety and product protection. As each Continuous Liner System is custom-built, it meets the requirements of every filling or packaging line as well as various isolators. It offers perfect protection for highly sensitive or bulk products such as active pharmaceutical ingredients or toxic and reactive products. The system is manufactured completely under ISO 5 at rest conditions (DIN EN ISO 14644-1) and guarantees cleanliness and containment. The process flow remains closed for safe and clean operations along all of your processes. CLS can be provided non-irradiated or pre-irradiated by Bischof+Klein for use in sterile applications. Bischof+Klein offers proper irradiation validation.

CleanFlex® pe bottle-shaped bags – size range

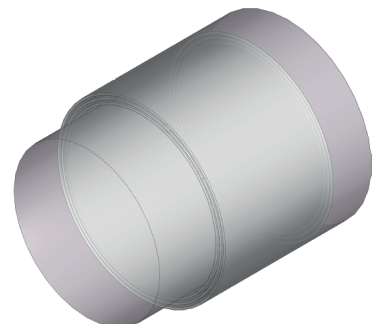
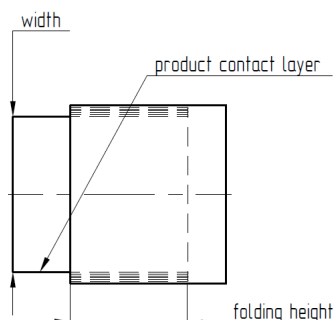
Type	External width	Film thickness	Folding height	CLS length
Minimum	200 mm	30 µm	As required by customer*	10 – 85 m
Maximum	1,400 mm	300 µm	As required by customer*	10 – 85 m

The indicated size range is intended as a guideline.
Each design has to be checked individually as regards feasibility.
*Custom-built, depending on the film thickness and length.

Material options

- CleanFlex® Idpe film (medical grade)
- CleanFlex® proteclen® cf film (non-migrating antistatic)
- CleanFlex® iap film (migrating antistatic)
- Additional additives such as anti-blocking agent
- Transparent compound (with PA or EVOH, etc.)
- Other film compositions (on request)

Attachment – conversion design example



Full traceability

- IR spectrum as proof of material origin
- Certificate of analysis for all production runs
- Full labeling of bundles and pallets
- Documentation of entire process

Tailored

- Thickness from 30 – 300 µm
- Antistatic, anti-slip, anti-blocking additives
- Customized sizes and packing

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

Clean room production

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

Regulatory compliance*

- USP < 661.1 >
- USP < 87 > and < 88 > class VI
- Ph. Eur. Monographs 3.1.3. and 3.1.4.
- 2011/ 10 / EC (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.

Laboratory options

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

Long-term stability analysis

- No change at different irradiation doses (25 – 75 kGy)
 - depending on material
- No change in physical properties (5 years)

Certification and quality assurance

- IR spectrum of LDPE film
- Dimensions and thickness
- ISO 9001: 2015
- ISO 15378 : 2017

Sterilization options

- Resistant to ethylene oxide gassing
- Resistant to plasma sterilization
- Resistant to E-beam sterilization
- Resistant to gamma irradiation
- Pre-sterilization can be arranged by Bischof+Klein
- Certificate of irradiation can be provided

Accessories

- Different conversion designs (please see example in attachment – further designs on request)
- Inclusion of rubber band into the film opening / closure
- Additional loose rubber band can be provided together with CLS
- Custom-built opening as well as closure designs
- Sampling 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.

