



## CleanFlex® bottle-shaped bags

CleanFlex® bottle-shaped bags have been in production for a number of years in the form of tailor-made packaging systems with special sealing radii and cut-and-finish seams. With their sealed, shaped shoulder, these bags are used wherever compatibility with a filling or pouring spout has to be guaranteed to achieve dust-free filling / emptying. One additional advantage is the optimum, complete emptying ensured by the diagonal seals around the neck. This is highly regarded, particularly when handling powdered, highly-sensitive, and expensive products. The bottle-shaped bags therefore offer ideal adaptability, in isolator production for example, while simultaneously providing high capacity in a compact format.

### CleanFlex® pe bottle-shaped bags – size range

Type	External width	External length	Filling spout width	Filling spout length
Minimum	200 mm	400 mm	125 mm	60 mm
Maximum	800 mm	1,700 mm	440 mm	600 mm

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

### Material options

- 100 % LDPE film, medical grade – standard: 100 µm
- Other film compositions and additives such as anti-blocking agent (on request)
- CleanFlex® Proteclen® CF antistatic PE film or CleanFlex® IAP antistatic PE film (on request)
- Transparent barrier films (with PA or EVOH)
- Tyvek® for steam sterilization processes

### 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\*

- USP < 661.1>
  - USP < 87 > and < 88 > class VI
  - Ph. Eur. Monographs 3.1.3. and 3.1.4.
  - Regulation (EU) Nr. 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 LDPE film
- Dimensions and thickness
- Seal strength
- Particle class 100 as per IEST-STD-CC -1246E
- 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 at different irradiation doses (25 – 75 kGy)
- No change in physical properties (5 years)



## Sterilization options

- Suitable for gamma irradiation
- Suitable for plasma sterilization
- Suitable for E-beam sterilization
- Suitable for steam sterilization (Tyvek)
- Suitable for ethylene oxide gassing (Tyvek)
- 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
  - Printing
  - Conversion
  - Bundling and packing



## Tailor-made

- Thickness from 60 – 300 µm
- Additives such as antistatic, slip, anti-blocking agents
- Customized printing
- Indicator labels for sterilization options

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

