



## CleanFlex® st pe flat bags

Polyethylene packaging is the easy solution for preventing contamination. When sealed, it provides perfect protection for bulk products and ensures the cleanliness level of the clean room as well. The clean room chain remains closed for safe and clean operations along all your processes. PE bags can be provided in non-sterile or pre-sterilized form by Bischof+Klein for use in sterile applications.

### CleanFlex® st – standard range

Code	External size	Internal size	Qty. / full pal.	Qty. / box
STPE15	150 x 230 x 0.080 mm	150 x 220 mm	36,010 pcs.	6,000 pcs.
STPE20	200 x 300 x 0.100 mm	200 x 290 mm	18,010 pcs.	3,000 pcs.
STPE30	300 x 500 x 0.100 mm	300 x 490 mm	6,010 pcs.	1,000 pcs.
STPE50	500 x 700 x 0.100 mm	500 x 690 mm	3,010 pcs.	500 pcs.
STPE60	600 x 800 x 0.100 mm	600 x 790 mm	2,410 pcs.	400 pcs.

### Standard packaging

- Bags in 2 protective bags
- Bundles in small cardboard boxes
- Pieces per pallet as listed above
- 10 customer samples per pallet
- Bundle labeled for traceability incl. gamma irradiation indicator

- STPE15: 100 bags / bundle
- STPE20: 100 bags / bundle
- STPE30: 100 bags / bundle
- STPE50: 50 bags / bundle
- STPE60: 50 bags / bundle

### Standard packaging

- 100 % LDPE film – medical grade

### Standard printing

- Bischof+Klein lot number for full traceability
- Transparent without ink
- „CLEANFLEX“

## 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

## 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

## 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.

## Long-term stability analysis

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

## 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
  - Printing
  - Conversion
  - Manual operations
  - Bundling and packing

## Tailored

- Thickness from 50 – 300 µm
- Additives such as antistatic, slip, anti-blocking agent
- Side-gusseted and pre-inserted multiple bags
- Customized sizes, shapes, prints, and packing

## Sterilization options

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



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.