



## CleanFlex® Proteclen® antistatic PE film

The Bischof+Klein special antistatic film based on a non-migrating agent. Proteclen® in form of films or converted bags provides safe and clean solutions for products specifically for the pharmaceutical and medical industry. Proteclen® – the safety concept for sensitive products and processes.

### CleanFlex® Proteclen® antistatic PE film – size range

| Type    | Width    | Thickness |
|---------|----------|-----------|
| Minimum | 300 mm   | 80 µm     |
| Maximum | 1,350 mm | 150 µm    |

### Antistatic properties

- In accordance with DIN EN 62631; (annular electrodes, arrangement as per Figure 3)
- Antistatic values as follows:  
Between  $> 10^4$  ohms and  $< 10^{11}$  ohms at 23°C and 30 % relative humidity

### Full traceability

- IR spectrum as proof of material origin
- Certificate of analysis for every production run
- 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\*

- Base material resin Ph. Eur. Monograph 3.1.3.
  - 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 film
- 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 (2 years)



## Sterilization options

- Suitable for ethylene oxide gassing
- Suitable for plasma sterilization
- Suitable for E-beam sterilization
- 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
  - Printing
  - Conversion
  - Bundling and packing



## Tailor-made

- Thickness from 80 – 150 µm
- Flat film, tubular film, flat bags
- 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.

