



CleanFlex® IAP antistatic PE film

Polyethylene packaging is the easy solution for preventing contamination. Internal Antistatically-equipped polyethylene Packaging (IAP) provides additional advantages for the end user of the packaging. Bischof+Klein has therefore developed a PE-based film with a migrating antistatic agent for its customers' special applications. The Bischof+Klein special antistatic PE film with a migrating antistatic agent. This Internal Antistatically equipped polyethylene Packaging in form of films or converted bags provides safe and clean solutions for products specifically for the pharmaceutical and medical industry. CleanFlex® IAP - the safety concept for sensitive products and processes.

CleanFlex® IAP antistatic PE film – size range

Type	Width	Thickness
Minimum	100 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 $> 10^8$ ohms and $< 10^{11}$ ohms at 23°C and 50 % 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
- 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.

