



CleanFlex® Headerbags

Microbiologically impermeable – but nevertheless breathable: Packaging made from Tyvek® ensures water vapor permeability for sterilization while offering microbiological impermeability and extensive resistance to abrasion and aging at the same time. Header bags in combination with Tyvek® lids/sheets offer a proven overall concept for sterilizing RTU syringes. Vapor and irradiation methods can be used for this, for example. An extensive range of optional equipment such as individual printing round off our portfolio.

CleanFlex® Headerbags – size range

Type	External width	External Length	Strip width (SW)
Minimum	100 mm	200 mm	140 mm
Maximum	600 mm	950 mm	400 mm

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

Material options

- A. Headerbag made from PET / PE and uncoated Tyvek®
 - ▶ Best closure integrity and physical stability
- B. Headerbag made from PE and uncoated Tyvek®
 - ▶ The most cost-effective version

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*

- 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 product contact layer
- Dimensions and thickness
- Seal strength
- Particle class 200 as per IEST-STD-CC-1246E
- ISO 9001: 2015
- ISO 15378 : 2017



Clean room production

- Particle and biological monitoring in place
- Qualification as per DIN ISO 14644-1 class 5, at rest:
 - Extrusion of film
 - Cleaning of Tyvek®
 - Cleaning of film
 - Optional printing on Tyvek®
 - Conversion
 - Bundling and packing



Long-term stability analysis

- No change in physical properties (3 years)



Sterilization options

- Designed for ethylene oxide gassing
- Suitable for plasma sterilization
- Suitable for gamma irradiation
- Pre-irradiation can be arranged by Bischof+Klein
- Certificate of irradiation can be provided



Tailor-made

- Customized printing
- Customized easy-opening options possible
- USP- and EP-compliant product contact layer on request
- Optional indicator print for ETO
- Other indicator labels and prints for other sterilization options



Laboratory options

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

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.

