

# CleanFlex®



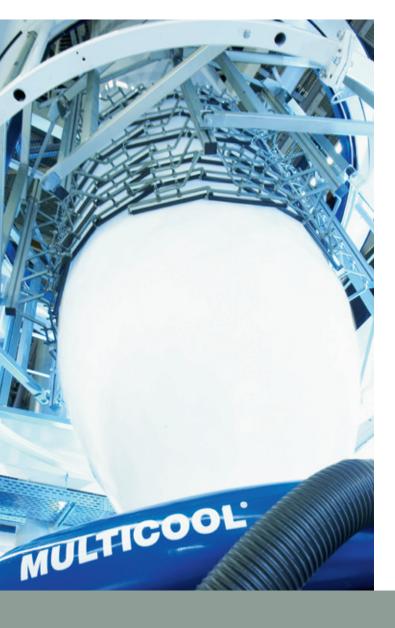
INNOVATIVE PACKAGING - TOP TECHNICAL PERFORMANCE

## THE SAFETY CONCEPT FOR HIGHLY-SENSITIVE GOODS

Sectors such as the pharmaceutical, medical and foodstuff, but also semi-conductor industries are characterised by innovation and continuous adaptation to current market requirements. New product developments constantly demand individual packaging solutions which securely and reliably protect the sensitive product.

Absolute cleanliness a basic demand of product quality – this must be unreservedly guaranteed! The requirement defined for our products is therefore "outstanding quality with maximum reliability and optimum usage".

We wish both to satisfy our customer and to thrill them with products of the very highest quality.



### **CLEAN ROOM PRODUCTION**

With our class 5 clean room production facilities in accordance with DIN EN ISO 14644-1 (=class 100 FED-STD 209 E), we offer lowgerm and low-particle production of our packaging material, guaranteeing "safety via extremely pure quality".

Our specially trained and motivated production teams are supported by our internal laboratory and testing facilities. Additionally all production and quality related processes are oriented towards GMP.

- · Low germ and low particle packaging.
- · Protection against external influences.
- · No contamination of your own clean room.
- · Finished products retain the purity in which you have invested.

Use of CleanFlex® therefore ensures a high level of product safety and quality by adhering to the clean room chain from the start of production until the product reaches your customer.

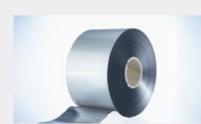
## **CLEANFLEX® PRODUCT RANGE**



High-barrier bags



Bottle-shaped bags



Laminates



Pre-inserted double bags



Tailor-made 3-in-1 system



## ENCAPSULATED **PROCESSES**

- · Extrusion of film
- · Printing of material
- · Cleaning and inspection of materials
- · Conversion of bags

- · Tailor-made finishing
- $\cdot \ \text{Final protective packing} \\$



CleanFlex® HeaderBags · for ETO sterilisation



GlovFlex







## Product related aspects:

- · Certificate of Analysis
- $\cdot$  Materials in compliance to EU regulations and FDA
- · Materials in compliance to EP and USP requirements
- · DMF for dedicated packaging materials
- · Particle testing on finished products on demand
- · Pre-sterilisation with gamma on demand

## Facilities related aspects:

- · Particle and microbiological monitoring of clean room
- · Integrated laboratory and test equipment
- · Pest control concept on all premises
- · Efficient cleaning procedures
- · Stringent change control policy









### **CERTIFIED QUALITY IS SAFETY**



By implementing the latest production, analysis and laboratory technologies, B+K achieves the very highest quality based on the most precise planning, checking and documentation of each individual production phase. Back in 1990, B+K became one of the first companies within the packaging industry to obligate itself to the concept of quality, establishing and certifying its QM system according to the DIN EN ISO 9000 ff series of standards. Since then, we have complied with all revisions to the standards and are now certified according to DIN EN ISO 9001:2008.



Active environmental protection has been a firm part of B+K's corporate philosophy since 1985. Since then, ecological, economic and social goals have been firmly anchored in the company's practices and are reflected in a number of successful environmental protection projects and measures. In 1987, B+K became one of the first companies in Germany to publish an environmental report, and has been continuously certified according to EMAS since 1996.



## WHAT B+K STANDS FOR

Bischof + Klein is one of Europe's leading full-service suppliers of flexible plastic and paper packaging and technical films. This family-owned company is represented around the world by a strong network of production plants and sales offices. Technicians and development engineers have access to a unique range of production opportunities at the company's headquarters in Westphalia's Lengerich. All processes for manufacturing flexible packaging are bundled under one roof here. The outstanding quality of our products, our flexibility and our unusual services are valued by our partners around the globe.

Our vision is to become the market's first choice for flexible packaging and technical films.





