

## CleanFlex®

INDUSTRIAL PACKAGING



THE **SAFETY CONCEPT** FOR **HIGHLY-SENSITIVE GOODS**

# CleanFlex®

## CLEAN ROOM PACKAGING FROM BISCHOF + KLEIN

Sectors such as the pharmaceutical and foodstuff 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.

However, other industrial sectors such as the electrical engineering, micromechanical and optical industries are also demanding increasingly higher-quality and higher-performance packaging which has to perform extremely specific functions.

Absolute cleanliness is the basic prerequisite 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 do not wish to merely satisfy our customers, but to thrill them with products of the very highest quality.**

Our class 5 clean room production facilities in accordance with DIN EN ISO 14644-1 (= class 100 FED-STD 209 E) offer low-germ and low-particle production of films, bags, sacks and liners, all of which guarantee "safety thanks to pure quality".

Talk to us about your CleanFlex® clean room packaging requirements!

Together, we will work out a tailor-made packaging solution for you.

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## CLEANFLEX® PRODUCT MANAGEMENT

## OUR CUSTOMERS

### REFERENCES - CLEAN ROOM PACKAGING

Altana Pharma (Nycomed), Singen	D
American Stelmi Corporation	USA
Baxter Oncology, Halle	D
Bayer AG, Leverkusen	D
Bayer Pharma S.p.a., Milano	I
Bayer Schering AG, Berlin / Bergkamen	D
Boehringer Ingelheim, Ingelheim / Roxanne	D/USA
Bristol-Myers Squibb S.r.L.	I
Chemtec Leuna GmbH, Leuna	D
CSL Behring GmbH, Marburg	D
Daiichi Sankyo Europe GmbH, München	D
DMV International	NL
Dyneon GmbH, Burgkirchen	D
Ferro Pfanzstiel	USA
Fresenius Kabi, Friedberg	D
Fresenius Medical Care, Bad Homburg	D
GEA Niro GmbH	D
Gerresheimer Bünde GmbH, Bünde	D
Gerresheimer Lohr GmbH, Lohr	D
Gerresheimer Wilden AG	D/CH
Getinge La Calhène	F
Girindus AG, Bensberg	D
GlaxoSmithKline Bio, Wavre/Rixentsart	B
Grünthal GmbH, Aachen	D
Helvoet Pharma	B
Hexal Syntech, Radebeul	D
F.Hoffmann – La Roche AG	CH
Janssen Pharmaceutical	B
Lonza AG, Visp	CH
Lonza Braine S. A	B
Lugaia AG, Visp	CH
Menarini Arzneimittelwerk, Dresden	D
Merck KGaA, Darmstadt	D
Merckle GmbH, Blaubeuren	D
Mundipharma GmbH, Limburg	D
Novartis Pharma GmbH	CH
Novartis SPM Pte Ltd.	SGP
Nuova Ompi (Stevanato Group)	I
P.E.T. Power	NL
Pfizer GmbH	D
Pliva	PL
Riwisa AG	CH
Roche Diagnostics GmbH	D
Rumpler Technologies / Stelmi	F
Sächsische Serumwerke (GSK Bio), Dresden	D
Sandoz Ind. Prod., Frankfurt	D
Sanofi Aventis Deutschland GmbH, Frankfurt	D
Sanofi Aventis Principes Actifs Pharmaceutiques	F
Schott Polymer GmbH / Forma vitrum	CH
Schwabe Extracta / Schwabe Arzneimittel, Karlsruhe	D
Schwarz Pharma Ltd.	IRL
Solvay Pharmaceuticals	D/NL
Stomil Sanok	PL
Transject GmbH & Co KG., Neumünster	D
West Pharmaceutical Services, Eschweiler	D

# CleanFlex®

## CLEAN ROOM PACKAGING

### LOW-GERM AND LOW-PARTICLE FILMS, BAGS, SACKS AND LINERS



#### We develop and produce:

- Single-wound and tubular films
- Open-mouth and side gusseted mitred sealed bags
- Bottle-shaped bags
- Two and three-ply bags
- Tyvek® / HDPE bags with three side seals, autoclavable
- Packaging with DMF



Low-germ and low-particle PE film extrusion



Printing under clean room conditions



Low-germ and low-particle bag production



Particle determination



Use of a bottle-shaped bag in packing penicillin

- Extrusion and conversion under class 5 clean room conditions according to DIN EN ISO 14644-1.
- Use of cleared raw materials in accordance with FDA and LMBG regulations.
- Internal laboratory and test facilities.

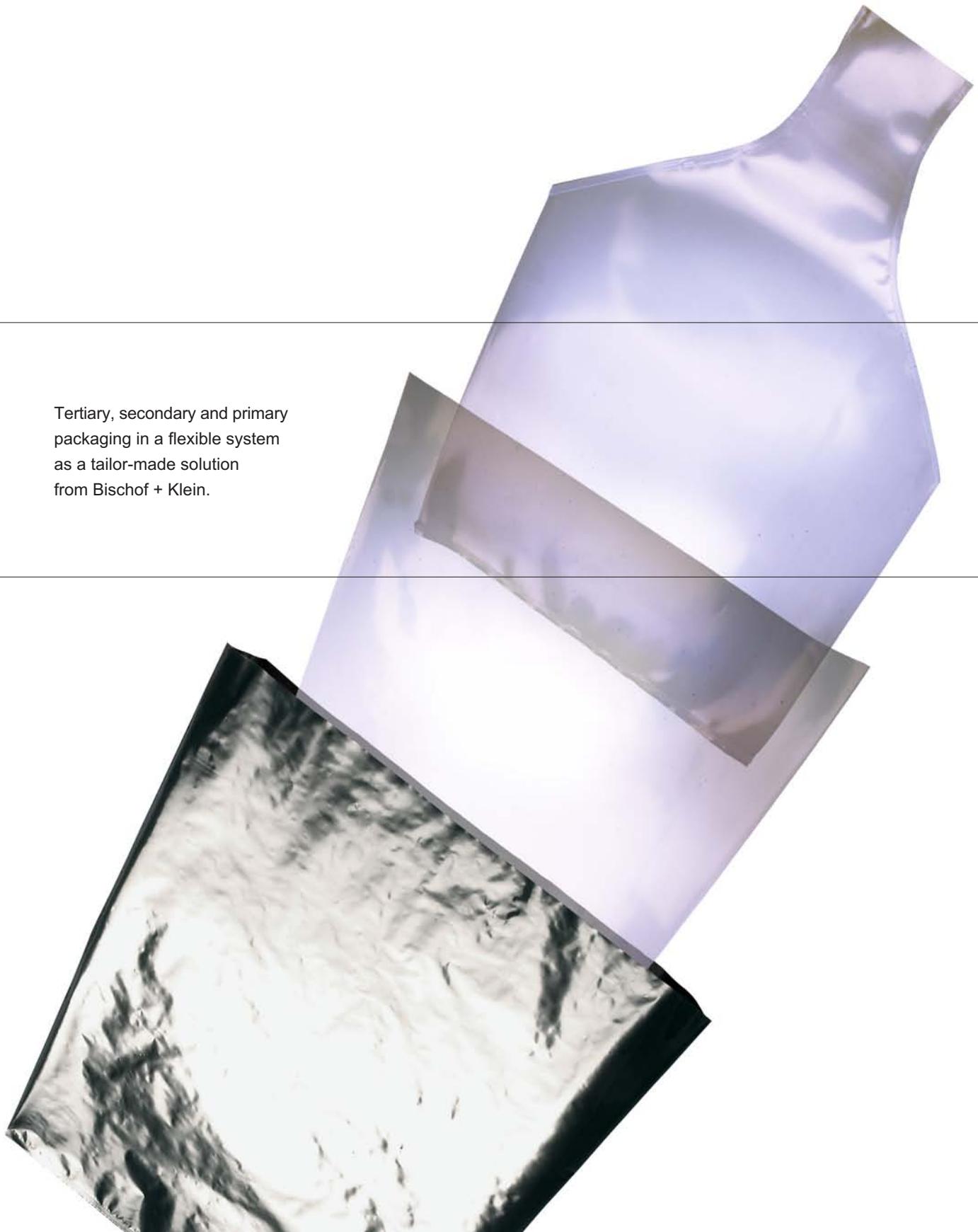
- GMP-friendly quality assurance at all levels.
- Certified to DIN EN ISO 9001:2000.
- Environmental management system according to EU Ordinance No. 761/2001 and EN ISO 14001:1996 Section 4.

# CleanFlex®

**3-IN-1 – THE COMPACT PROTECTION SYSTEM**

LAMINATED ALUMINIUM LINERS, PE FLAT LINERS AND BOTTLE-SHAPED BAGS

Tertiary, secondary and primary  
packaging in a flexible system  
as a tailor-made solution  
from Bischof + Klein.



# CleanFlex®

## TWO-PLY BAGS

PACKAGING FOR THE SEMICONDUCTOR INDUSTRY



Ready to use – pre-manufactured two-ply bags for packaging in clean rooms. Silicon wafers and blocks are protected against contamination and damage.



# CleanFlex®

**TYVEK®/HDPE BAGS**

**WATER VAPOUR AUTOCLAVABLE PACKAGING**

Plastic and rubber stoppers are sterilised in the bag using water vapour. The seals can be used directly. The change in colour in the printed sterility indicator guarantees successful sterilisation.



braun = sterilis.  
brown = sterilize.  
brun = stérilisé.  
bruno = steril.  
marrón = sterilisé.

# CleanFlex®

## THREE-SIDE SEALED BAGS

HIGH-BARRIER PACKAGING MADE OUT OF DIFFERENT LAMINATIONS



Thanks to their high water vapour and oxygen barrier, three-side sealed bags made out of different lamination offer their contents optimal protection against moisture and aromas. They additionally offer absolute light protection and the option of vacuum-packing their contents.



## GLOBAL PACKAGING COMPETENCE

Packaging solutions from the B+K-GROUP are at home throughout the entire world.

With a strong network of production plants and sales agencies, we are a leading European full-service supplier of flexible plastic and paper packaging. Customers around the globe value the outstanding quality of our products and our extraordinary services.

Our unique product portfolio ranges from traditional industrial packaging and consumer packaging to special films for technical applications.

From optimised, cost-effective solutions for major consumers to individual special products - in close co-operation with our partners, we develop and manufacture over 10,000 packaging variants which precisely meet our customers' specific requirements. We regard meeting even the most extraordinary customer and market requirements with creative, cost-effective and recycling-friendly packaging solutions as a constant challenge.



Bischof + Klein's competence is backed up by over 80 years of experience in developing and producing packaging. This tradition enables us to offer our international customers what they have come to expect from a progressive and innovative packaging company:

Outstanding quality, technological innovation and uncompromising service throughout the entire process chain.

This is the standard which we strive to achieve on a daily basis. It is equally applicable today as it was 80 years ago and will remain in the future.



# C E R T I F I C A T E

**DQS GmbH**

Deutsche Gesellschaft zur Zertifizierung von Managementsystemen

hereby certifies that the company

**Bischof + Klein GmbH & Co. KG**

Rahestraße 47  
D-49525 Lengerich

Industriestraße 1  
D-94357 Konzell

for the scope

Production of films and packaging

has implemented and maintains a

**Quality Management System.**

An audit, documented in a report, has verified that this quality management system fulfills the requirements of the following standard:

**DIN EN ISO 9001 : 2000**

December 2000 edition

This certificate is valid until 2008-11-15

Certificate Registration No. 004869 QM

Frankfurt am Main 2005-11-16

Ass. iur. M. Drechsel

MANAGING DIRECTORS

Dipl.-Ing. S. Heinloth

D-60433 Frankfurt am Main, August-Schanz-Straße 21



# IQNet

<sup>®</sup>

THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

**IQNet** and

**DQS GmbH** Deutsche Gesellschaft zur Zertifizierung von Managementsystemen  
hereby certifies that the company

## **Bischof + Klein GmbH & Co. KG**

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- IQNet -  
THE INTERNATIONAL CERTIFICATION NETWORK

Dr. Fabio Roversi  
President of IQNet

Ass. iur. M. Drechsel  
Managing Directors of DQS GmbH

S. Heinloth

IQNet Partners\*:

AENOR Spain AFAQ France AIB-Vinçotte International Belgium ANCE Mexico APCER Portugal CISQ Italy CQC China CQM China  
CQS Czech Republic Cro Cert Croatia DQS Germany DS Denmark ELOT Greece FCAV Brazil FONDONORMA Venezuela  
HKQAA Hong Kong ICONTEC Colombia IMNC Mexico IRAM Argentina JQA Japan KEMA Netherlands KFQ Korea MSZT Hungary  
Nemko Certification Norway NSAI Ireland ÖQS Austria PCBC Poland PSB Certification Singapore QMI Canada RR Russia  
SAI Global Australia SFS Finland SII Israel SIQ Slovenia SQS Switzerland SRAC Romania TEST St Petersburg Russia  
YUQS Serbia and Montenegro

IQNet is represented in the USA by the following partners: AFAQ, AIB-Vinçotte International, CISQ, DQS, KEMA, NSAI, QMI and SAI Global

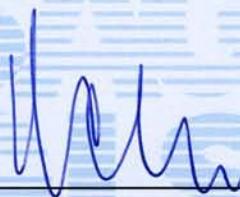
\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)

# Hygienic Certificate

The company  
**Bischof + Klein GmbH & Co. KG**

is under hygienic control of the  
Labor L+S Laboratory

Last monitoring: 09/2007



Dr Gero Beckmann



Melanie Braun (QA)

NIEDERRHEINISCHE INDUSTRIE- UND HANDELSKAMMER  
DUISBURG WESEL KLEVE ZU DUISBURG

ALS GEMEINSAME REGISTERFÜHRENDE STELLE VON INDUSTRIE- UND HANDELSKAMMERN  
IN NORDRHEIN-WESTFALEN NACH UMWELTAUDITGESETZ  
- REGISTRIERUNGSSTELLE -

# Certificate of Registration



Bischof + Klein GmbH & Co. KG

with the Sites

Rahesträße 47  
49525 Lengerich

and

Industriestraße 1  
94357 Konzell

Registration-No.: DE-156-00009

Date of first registration  
5<sup>th</sup> June 1996

This certificate is valid until  
14<sup>th</sup> May 2011

This organisation has established an environmental management system according to EU-Regulation Nr. 761/2001 and EN ISO 14001:2004 section 4 to promote the continual improvement of environmental performance, publishes an environmental statement, has the environmental management system verified and the environmental statement validated by a verifier, is registered under EMAS and therefore is entitled to use the EMAS-Logo.



Duisburg, 5<sup>th</sup> June 2008

Dr. Stefan Dietzelbinger  
General Manager