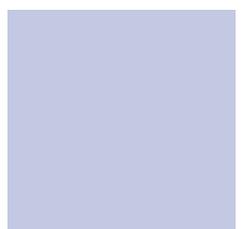
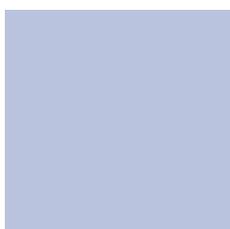
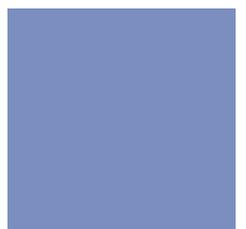
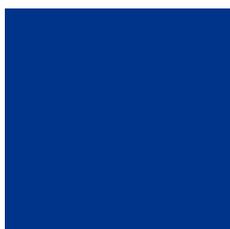
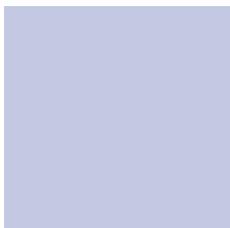
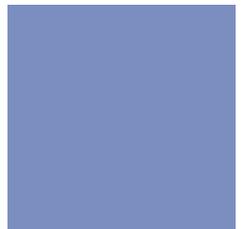
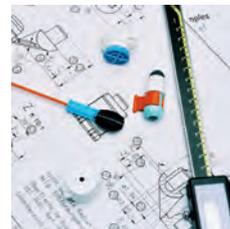
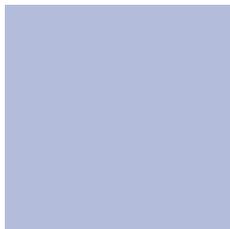
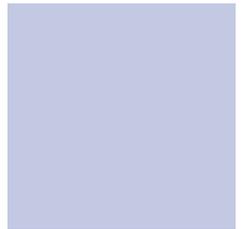


# transcoject®

MEDICAL DEVICES AND  
PHARMA PACKAGING SOLUTIONS

ONE STOP } DESIGN } MOULDING } FILLING } PACKAGING } STERILIZATION



## TRANSCOJECT, A STORY OF INNOVATION AND QUALITY

Transcoject's headquarters have been located in **Neumünster, Germany** since its foundation in 1969 by Karl-Heinz Rolle and Sven Husted-Andersen. Here in the beautiful "land between two seas" you find people for whom the most important values are openness and responsibility. At the same time the close proximity to Hamburg is reflected in our

work: with a typically hanseatic mix of care, candidness and foresight Transcoject has set **new standards in medical technology**.

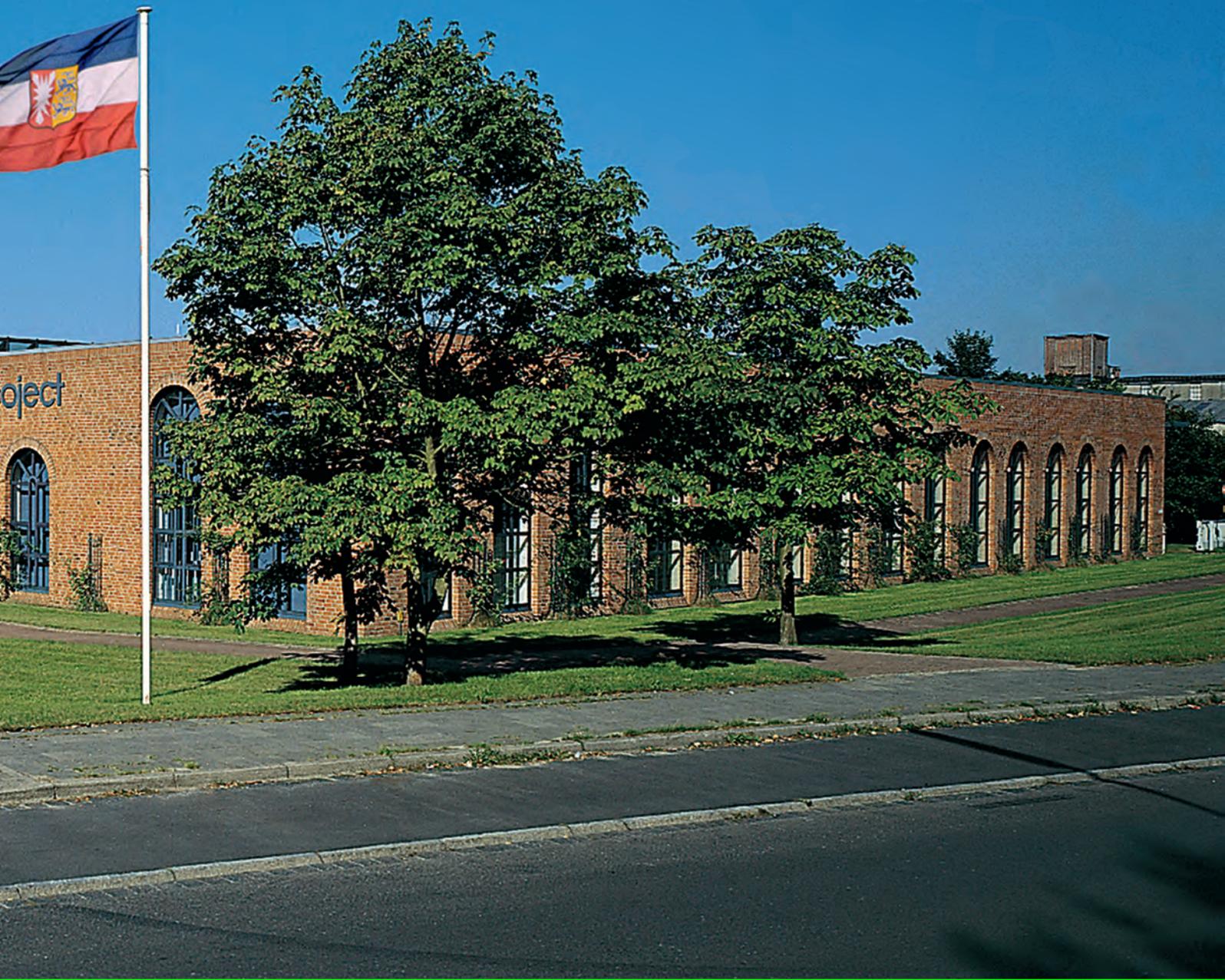
In 1972, Transcoject was one of the first manufacturers of plastic disposable syringes. The first filling line was completed in 1989 with the consistent implemen-



tation of the concept “from design to sterilized, filled syringe – **one stop**”. One of the first high-performance facilities producing 50 million syringes per year was commissioned in 2004, expanding the mass production of high-quality precision syringe systems. In 2005, Transcoject extended its product range and began manufacturing ready to fill syringes and cartridges made from cyclic polyolefins (COC/COP) in state-of-

the-art clean rooms. The dental product sector was split-off in 2008, into an independent company Transcodent that has become Transcoject’s customer.

Our highly qualified employees will strive to deliver the high-quality products as well as innovative solutions to meet customers’ demands from our base location in Northern Germany.



„Our company philosophy:  
first-class quality and  
continuous development.“

Dr. Christian von Falkenhausen  
(CEO of Transcoject GmbH)

## TRANSCOJECT – WHAT DRIVES US

Products with the highest quality standards are essential where technology comes into close contact with people, as it does in the medical field. Transcoject has developed custom solutions for plastic medical products and pharmaceutical primary packaging for over 40 years with the responsibility for the **welfare of the patient** and in the awareness that our efforts contribute substantially towards the prevention, early detection and treatment of diseases.

The **reliability and quality** of products that meet our customers' specifications are our daily challenge. Our production runs along the lines of GMP criteria and we are constantly working on the optimisation of our processes in order to be able to deliver the very best possible quality.

We are convinced that the best quality for the end product can be ascertained when the know-how and the entire production process is concentrated in one company. We are therefore in the position as one of few companies worldwide, to offer our customers one stop: design, moulding, filling, packaging, sterilization.

We can trust our employees to implement this high quality standard. As a **cosmopolitan family company**, we appreciate the value of the long-term personal relationship with our employees, which is characterised by a strong identification with the company and its products. Our employees are the cornerstone of our success and of the quality of our products.



**Design**



**Moulding**



**Filling**



**Packaging**



**Sterilization**

# Innovation – ideas that work



*COP, the right plastic  
for solutions featuring  
barrier functionality.*

*Our team of experts will find  
the right solution for you.*



## FLEXIBLE SOLUTIONS ON DEMAND

Ideas, concepts, materials and technologies, processes and costs: whoever wants to be successful with innovative products must have an ability to juggle these balls. Extensive technical know-how and **development experience** gained over many years have allowed us to develop design-inspired and economically expedient products that meet all of our customers' needs. Faultless functionality, optimal ergonomics and maximum safety is always incorporated.

Transcoject will **accompany, assist and advise** you from development of the first idea to the definition of requirements, determination of time appreciation and cost scheduling, right up to production. We will work in close dialogue throughout all stages of the development process. The tools consistently implemented are high-end CAD systems, diverse types of **sample production** and testing technology in conjunction with project organisation and documentation which fulfil all requirements.

However, our most valuable asset is our highly-qualified staff who consistently accomplish outstanding realisation quotas, even in the most complex development projects.



*Transforming innovative ideas into reliable products.*

Our product:

# quality non-stop



*Our precision injection  
moulding – fulfilling  
highest quality standards.*

*Our moulds – the  
basis for non-stop  
precision.*



## BEST KNOW-HOW IN INJECTION MOULDING

Plastic articles, which we manufacture with **precision injection moulding**, are the core of our product range. This only takes place in clean rooms, which are classified according to current GMP pharmaceutical standards. Our validations are naturally also conducted in accordance with applicable GMP standards.

Due to the diversity of our machinery and the qualification of our employees, both small series as well as larger campaigns up to 50 million pieces per year can be produced without compromising on the quality in a three-shift system. This is verified by the implementation of constant monitoring and continual quality checks.

As a leading manufacturer of disposable syringes and customer-specific application systems for the medical and dental fields, we exclusively utilise **top quality raw materials** and components sourced from eminent international manufacturers and suppliers. This enables us to safeguard the optimal application safety of all products. It also remains a focus in our ongoing development: **patient safety** is paramount to the development and realisation of product innovations.



*Continuous and meticulous maintenance of our moulds safeguards the quality of your product.*

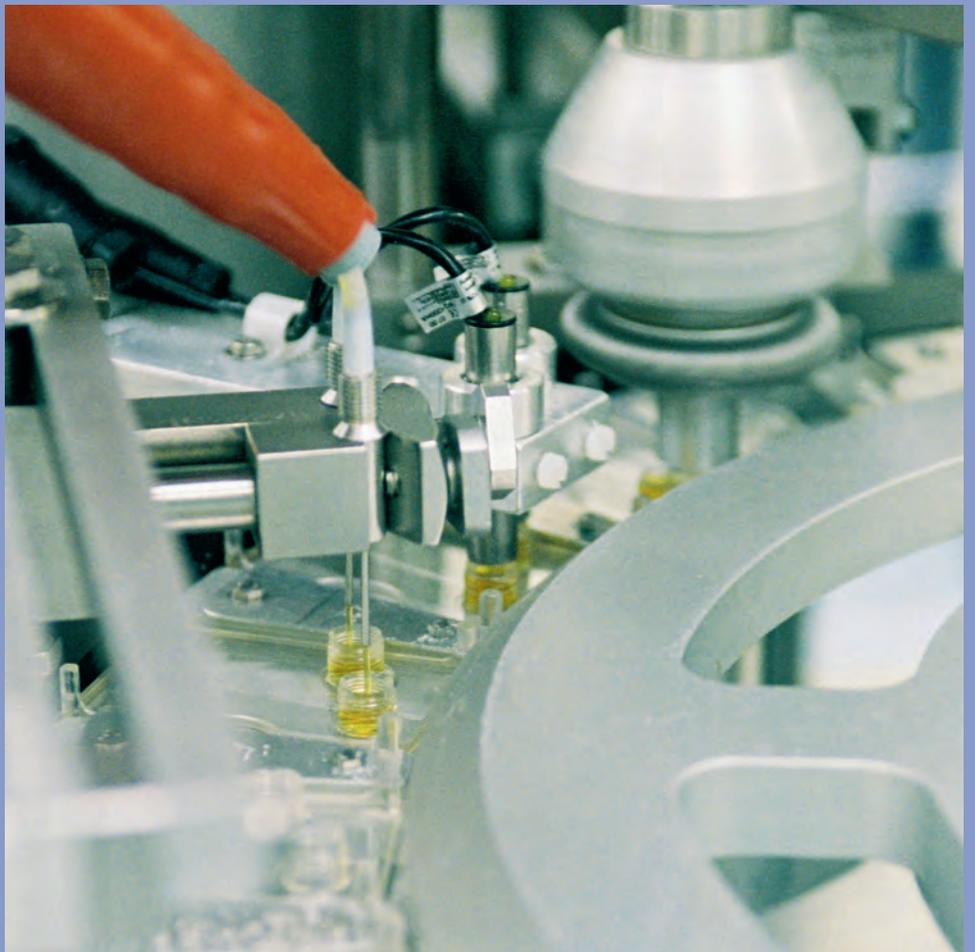
### Accurate to the smallest detail – our tools

Quality products can only be produced with quality tools. Therefore, we do everything possible to meet our standards for injection-moulding tools and follow-up automation, in order to guarantee the best quality for our customers. Our highly-qualified personnel construct everything in accordance with requirements, from pilot tools to filling stations in our own **technology centre**. Our production equipment is thus tailored to your needs: efficient while remaining flexible.

# Qualified, validated, certified – aseptic filling



*The vast experience of  
our employees warrants  
continuous quality during  
the formulation of the  
filling medium and the  
filling process.*



## FILLING IS A MATTER OF TRUST

A logical, if not common step for a manufacturer of medical devices and pharmaceutical primary packaging is to also provide the filling of these products. Our spectrum in this sector currently ranges from **in-vitro diagnostic medical devices** to the ready to use syringe. Hence, we develop custom containers for auto-sterile solutions, design and construct an appropriate filling station and fill on site. The filling medium is provided by the customer or can be formulated in our adjacent laboratory.

In the **aseptic filling** sector, the best quality, upmost safety and flexibility in order to meet diverse customer requirements are also a matter of course. Our **certification** according to ISO 13408 and GMP environments of Class A and B allows us to fill liquids of different viscosities in volumes from small series up to batch sizes of several hundred litres. The packaging thereof is predominantly produced and sterilised in-house.

The aseptic filling, as a particularly critical procedure, requires exhaustive qualification and **validation**. Transcoject guarantees this throughout all process steps and safeguards this by incorporating regular "media fills". Specially selected and trained staff safeguard that our customers' trust in these sensitive products is always justified, especially as the micro-biological monitoring is accomplished in-house.

The package is rounded-off with **comprehensive support**, which we offer our customers in order to aid them with obtaining the certification or authorisation to different markets. Transcoject offers an extensive and customer-focused one-stop service.

*It goes without saying that any sterile filling, even for the smallest batch sizes, is effected under laminar flow conditions.*



# Packing it – your way

*Customised packaging  
of your products is  
carried out under the  
most stringent clean  
room conditions.*



*Our high-performance equipment  
enables us to manufacture and  
package up to 50 million syringes  
per year.*

## INTELLIGENT DESIGN FOR FUNCTIONAL PRODUCTS

Plastic articles are transformed into **fully-functional** end products in this department. Whether screen or offset printing, siliconisation or ultrasonic welding, products are completed and the quality continuously monitored via manual or fully-automated systems.

For some products, specific production lines are employed, where all production stages are integrated into one machine, from injection moulding to testing and subsequent packaging. Our **machine construction** unit guarantees maximum flexibility and production safety by reducing our dependency on suppliers. Packaging is becoming more important for the conveyance of information, as a means of protection for products, in combating counterfeiting and as an aid in differentiation. Especially in the growing homecare market, the sensible arrangement of individual parts in **application sets** greatly contributes to safe and easy use.

We have specialised in the packaging of your products as a full-service provider in the field of medical technology, realising fully-packaged sets which are intelligently designed, custom printed and ready for use.



*We guarantee the highest quality of your products, at all times.*

# Certainly sterile



*We hold years of experience in the development and implementation of diverse sterilization cycles.*



## EXPERIENCE AND MODERN TECHNOLOGY – A WINNING COMBINATION

Transcoject has been a reliable partner in the ethylene oxide sterilization of thermo-sensitive products for the medical and pharmaceutical industries for over 40 years. We have been sterilizing products in a **dual-chamber system**, each with a volume of 33 m<sup>3</sup>, in various cycles according to ISO 11135-1 for the past decade.

Our experienced team of experts advise and assist our customers from the individually tuned **development of a customised sterilization cycle** right up to product sterilization. This also includes the microbiological examinations in our own laboratories.

Transcoject is your full-service partner in the ethylene oxide sterilization sector, with our wide range of customised services.

*Our comprehensive quality assurance system upholds the observance of all applicable norms during ethylene oxide sterilization.*

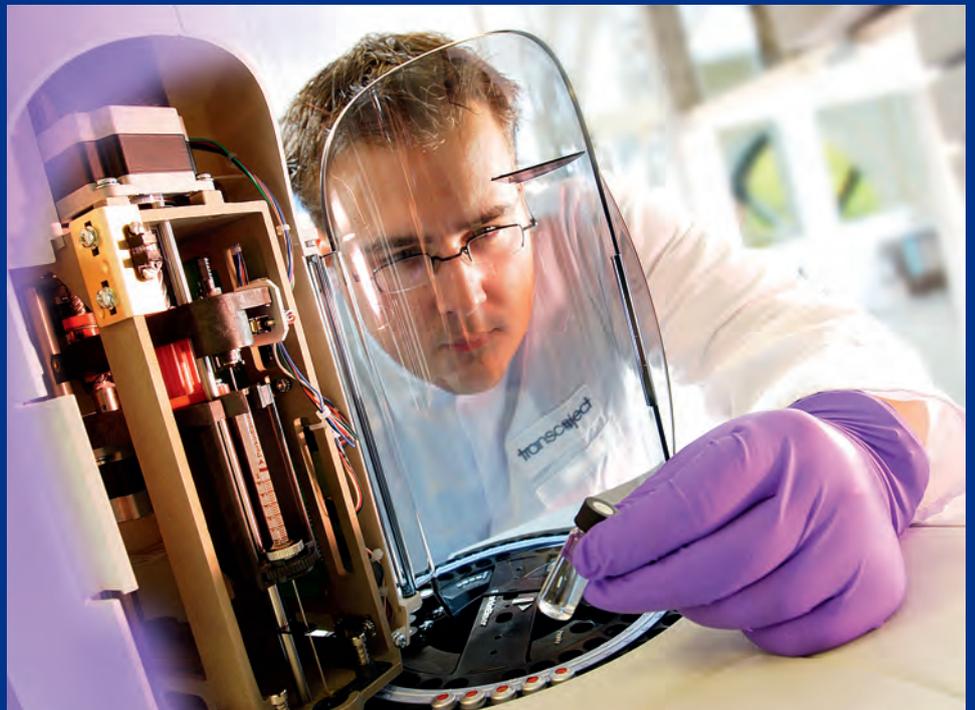


# STERILIZATION

# Quality – the foundation of our success



*Our 180 highly qualified employees are the cornerstone to our success. Their contribution to the quality of your products is indispensable.*



## OUTSTANDING QUALITY – WITHOUT COMPROMISE

As a manufacturer of high quality medical devices, it is our goal and commitment to consistently and exclusively deliver products of outstanding quality to customers and patients. For this reason Transcoject maintains a carefully conceived and comprehensive **quality management system** that is aligned with current GMP guidelines.

Successful quality management for Transcoject is a broad concept that incorporates all processes and activities of the company. The crucial element of our success and the quality of our products is our knowledgeable personnel. We ensure that **our employees' qualifications** are updated on a regular basis by means of targeted education and training. Each of our 180 employees is actively involved in the quality system and understands his responsibilities as being essential for the production of outstanding quality medical products.



*We safeguard the high quality of your products by continuously monitoring the production process.*

### Certification

As a manufacturer of medical devices, Transcoject is certified according to Directive 93/42/EEC Annex II and Annex V.

Our quality management is certified according to medical device standard ISO 13485:2003 and the general standard ISO 9001:2008

Our ethylene oxide sterilization is certified according to ISO 11135-1.

As a supplier of aseptic filling of medical devices, Transcoject is certified according to ISO 13408-1.

## OUR BASIS FOR FIRST-CLASS QUALITY:

The consistently high standard of our products is the result of carefully planned and **systematically controlled processes** in the administrative and technical fields. These are executed by a highly qualified and motivated staff, under consideration of all regulatory requirements.

- Our production is aligned with GMP requirements. The qualification of equipment and the continuous validation of processes is the basis for the manufacture of our high-quality products.
- Continual monitoring, critical reviewing of existing processes and the implementation of new processes and technology guarantee the compliance with highest quality standards.
- We test all products against the most stringent quality requirements, in our modern laboratories, before they leave our premises.
- We maintain both a microbiological and an analytical laboratory, both equipped with the latest appliances and equipment. Regular calibration of equipment and validated test methods is a matter of course.
- Extensive clean room monitoring guarantees that the production is conducted under GMP-compliant production surroundings.
- Regular in-process inspections during all production stages secure the product quality throughout the value creation chain.
- A validated document management system increases the transparency of the quality management throughout the entire company and allows quick access to corresponding documents.

**Our “One-Stop: Design, Moulding, Filling, Packaging, Sterilization” production chain is the key to our high quality standard.**

DESIGN



MOULDING



FILLING



PACKAGING



STERILIZATION



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