

KraussMaffei

HIGHEST PRODUCT QUALITY AND NO COMPROMISES

Solutions for the life sciences sector



PARTNERING WITH INDUSTRY

KraussMaffei is a premium partner for the plastics and rubber processing industries worldwide

Whatever you aim to achieve in plastics or rubber processing, KraussMaffei is your partner. We are the only company in the market with expertise in the three major machine technologies for plastics processing – injection moulding, reaction processing and extrusion. We continually integrate this know-how across the different technologies to develop new processes and machinery for plastics and rubber processing.

People for plastics

We are the “people for plastics”. We are your partner from the first exploratory discussion, through development of the optimal solution to commissioning, servicing and operating your system, including moving and final disposal of your system. At all times, you are assured of outstanding competence in planning and engineering, reliable spare parts logistics and fast-response service and support.

Commitment to customers

Cutting edge technologies and outstanding machinery are one part of the answer – comprehensive support by experts committed to your interests is the other. Our know-how is based on many decades’ experience and steady investment in research and development. We deliver what you need – from the product idea to a customer-specific system solution.

Adding value for customers

We put our expertise to work for your success. With machine ranges engineered for modularity, we can deliver application-specific solutions based on our wide range of standard modules and specially engineered solutions. This strategy offers customers technical and cost advantages.

Close to customers around the world

As an international company, KraussMaffei has a presence in all the major markets for the plastics and rubber processing industries and employs over 3,000 people worldwide. Our sales and service network keeps us close to all our customers around the world.

SECTOR-SPECIFIC SOLUTIONS

KraussMaffei solutions are as diverse as the challenges facing our customers



Automotive

Automotive components for all vehicle areas – chassis, cockpit, frame and engine compartment – are made on KraussMaffei machines and systems. Over 500 companies from the global automotive and automotive components industry are among our customers.



White Goods

Efficient thermal insulation is a key factor in reducing the power consumption of fridges, freezers and chillers. PUR rigid foam systems ensure optimal insulation even in relatively thin layers. KraussMaffei Italiana is a competence center for PUR rigid foams.



Construction

Plastics are widely used in the construction industry, where they offer striking benefits, such as light weight, weather- and UV-resistance, impact resistance, resistance to scratching, easy installation and good thermal insulation. Many construction plastics are extruded and here customers can count on productive solutions from KraussMaffei.



Life Sciences

Products for the healthcare and pharmaceuticals industries must be manufactured to stringent cleanliness and quality standards. With many years' experience, our expertise in compliance and cost-effectiveness is second to none. Our system solutions are qualified for high cleanroom classes.



Electrical / Electronics

The electrical and electronics industries make extensive use of plastics. They produce a huge range of plastics products, often with highly specialized properties. Optimal electrical insulation and resistance to thermal and mechanical stress are among the key properties.



Packaging

Plastics open up endless possibilities for packaging. They are extremely lightweight, design potential is limitless and recycling is unproblematic. Many companies operating in the packaging industry are longstanding KraussMaffei customers.

Our common goal in medical and cleanroom technology: operational excellence through zero defect tolerance

Absolute repeatability through totally transparent processes

The starting point for outstanding products for life sciences applications is the impeccable quality and traceability of the substances and products used. Quality compliance must be documented at every stage of the manufacturing process. Following Good Manufacturing Practice (GMP) regulations guarantees product quality and supplies the necessary assurance that the product is in compliance with the binding standards imposed by regulatory authorities.

For this reason, complete documentation of all phases of the qualification process is part of all KraussMaffei solutions for the life sciences sector. We will ship a factory-qualified machine complete with the required documentation. And you can rely on our expert support throughout the subsequent qualification processes – right through to performance qualification. You can be sure of a transparent production process, long-term repeatability within the tightest tolerances and more certainty for our common goal of operational excellence.

Quality to cleanroom Class 5

KraussMaffei offers a range of application-specific processes and solutions for implementing cleanroom production areas up to Class 5 (DIN EN ISO 14644-1) or Class 100 (US Federal Standard 209). We are the only machine supplier with a substantial track record of successful implementations. Our own advanced manufacturing processes, based on synchronized flow assembly, enable us to build our machines to rigorous quality standards, and to monitor and document this quality.

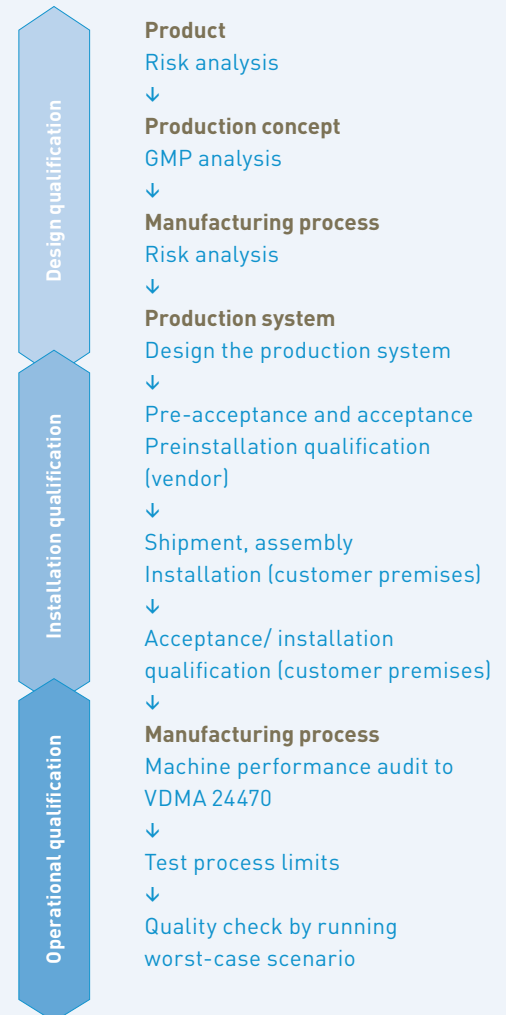
With comprehensive documentation and impeccable qualification of all process steps, KraussMaffei supports your drive for uncompromising product quality and highest repeatability.

**The complete value-added chain
from one supplier**

From raw material to finished product, the KraussMaffei Group offers you a comprehensive portfolio of solutions. In the life sciences industry, applications currently range from embedding pharmaceutical substances in carrier materials to manufacturing inhalers and medical tubing, sterile containers and blister films. We believe that the starting point for your high-quality products is the right combination of production solution and material. KraussMaffei is the only company worldwide with comprehensive engineering expertise in three key fields of plastics and rubber processing, combined with the ability to exploit potential synergies between them.

Life sciences is one of the sectors where you benefit most from the support of a partner knowledgeable in both material formulations and product design. Know-how and efficient communication can significantly shorten product development cycles. ‘Friction losses’ in the course of the project are kept to a minimum and you profit from consistent product quality for your entire process chain. The following pages will give you an insight into what KraussMaffei can offer you – and an overview of the processes and products we supply for companies operating in the life sciences sector.

**Good Manufacturing process (GMP)
qualification stages and relevant actions**



Not just a feel-good factor.
Cleanliness saves lives.





KraussMaffei supplies processes and machine solutions in compliance with high cleanroom classes. The number of airborne particles, pollen,

bacteria, viruses and aerosols that might be deposited on the surfaces of the plastic product can be rigidly controlled.



CUSTOMER:

Mapa GmbH

PRODUCT:

Disposable teat for baby feeding bottle for hospital use

FEATURES:

The teat is made of two materials: a TPE nipple plus a PP screw ring

CUSTOMER BENEFITS::

No post-mould sterilization required

REAL-LIFE SOLUTIONS

Baby feeding bottle for Mapa: no sterilization required

The background

Mapa, a manufacturer of products, eg, dummies and feeding bottles, brought its innovative idea for a feeding bottle teat to KraussMaffei and challenged us to develop a cost-competitive manufacturing solution.

The product

Disposable teat for baby feeding bottle for hospital use – with a TPE nipple and a PP screw ring.

The task

Develop a teat combination similar to a conventional latex disposable teat, but made of TPE, and plan the process to include aseptic packaging for each teat.

The challenge

Previously teats were sterilized post-mould using hydrogen peroxide to achieve the required sterility. The same outcome had to be achieved by production in a cleanroom environment – without post-mould sterilization.

The solution

Cleanroom production with a KraussMaffei two-component CleanForm injection moulding system including automation – planned for this customer and with product-specific modifications. Fully automated cleanroom production and aseptic packing – eliminating airborne dust particles, pollen and pathogens that could contaminate the plastic surfaces – eliminates the need for post-mould sterilization.

The benefits

Sharply reduced manufacturing effort, simplified logistics and a non-allergic product without the need for cost-intensive post-mould sterilization.

The outcome

The manufacturing process for teats has been optimized, compared with a conventional process. The result for Mapa is a very cost-effective, flexible and effective manufacturing process.



The decision to invest in a KraussMaffei cleanroom production cell has saved Mapa around 50% of the cost of the alternative, a conventional production line.



**Producing shatterproof containers
for precious fluids**



KraussMaffei machinery and systems deliver products that meet the exacting quality standards required in the life sciences sector, for example through continuous repeatability within the tightest

tolerances. They also open the door to products with enhanced usability, for example, a low risk of breakages.



CUSTOMER:

Scandinavian Health Limited (SHL Group)

PRODUCT:

Disposable auto-injector DAI™

FEATURES:

Meet stringent quality standards and maintain absolute repeatability for high-volume production

CUSTOMER BENEFITS:

Consistently high product quality within tightest tolerances by complete certification of all components and production systems

REAL-LIFE SOLUTIONS

Next generation drug delivery system by SHL: Absolute repeatability in partnership with KraussMaffei

The background

For over 14 years, Scandinavian Health Limited (SHL), has designed, developed and supplied advanced drug delivery systems for the international pharmaceutical and biotech industries. KraussMaffei partnered with SHL to implement production of a new disposable auto-injector.

The product

The Disposable Auto-Injector DAI™ enables patients to easily and efficiently inject themselves with drugs to treat a range of illnesses. The device consists of approximately 10 plastic components produced exclusively on KraussMaffei machines.

The challenge

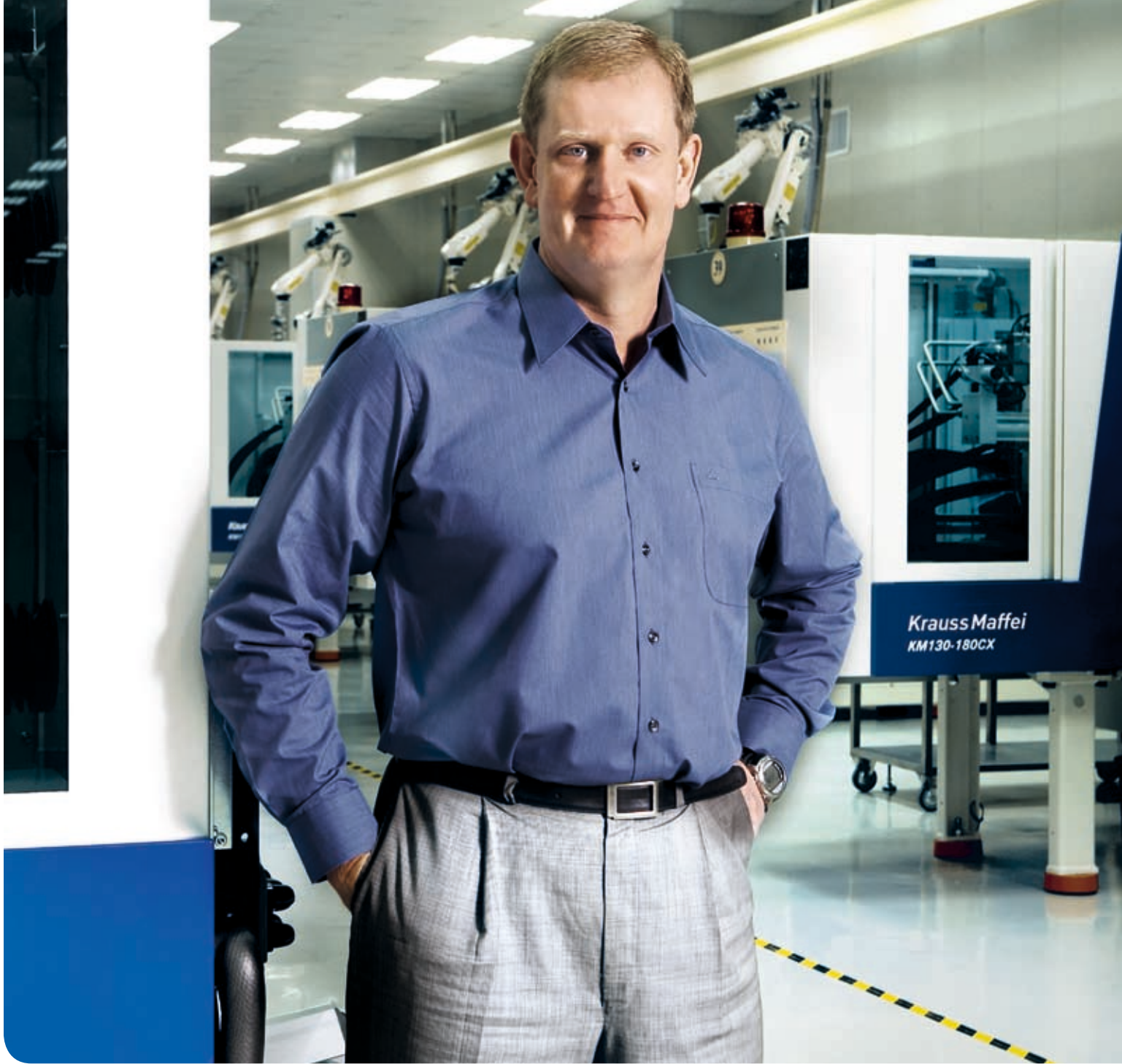
The SHL Group must be able to mass-produce product components, uphold stringent quality standards and maintain absolute reliability of the product, producing 24 hours a day, 365 days a year. In order to achieve this, production systems had to meet SHL's detailed specifications for all components and the whole production infrastructure had to be certified to the required standards.

The solution

KraussMaffei supplied cleanroom production cells precisely to the customer's specifications. The CX CleanForm injection moulding machines in different tonnages were fully certified as to product quality and performance. The production cells met all the customer specifications – from permissible component types to noise emissions and shot weight tolerances for the injection moulding machines.

The outcome

SHL, a leader in the global market, produces disposable auto-injectors for its customers in very high volumes. The company now operates over 100 machines engineered to the specifications that were drawn up in consultation with KraussMaffei. The constant delivery of excellent products has become a hallmark of the group's operations and a benchmark in the advanced drug delivery industry.



“As a global provider of drug delivery systems, strictly reproducible product quality is necessary for our existence. We have a policy of zero error tolerance and our partners have to share this thinking. KraussMaffei is such a partner.”

Roger Samuelsson, CEO and founder of the SHL Group

When simply “clean” is not enough





By systematically eliminating sources of contamination, KraussMaffei configures solutions for mass production in cleanroom environments

up to Class 5 to manufacture products that meet very high asepsis criteria.



CUSTOMER:

Rexam Pharma GmbH

PRODUCT:

Plastic container for injectable medication

FEATURES:

Ready-to-fill (clean and sterile) vial made of COC with TPE closure

CUSTOMER BENEFITS:

Efficient class 5 cleanroom, achieved by separating maintenance and production areas, minimizes contamination, even before gamma sterilization

REAL-LIFE SOLUTIONS

Container for injectable substances for Rexam: High cleanroom classes

The background

Rexam is the world's second largest consumer packaging group and a specialist in healthcare and medical packaging. The company was selected to manufacture Aseptic Technologies' newly developed Crystal® vial for injectables, under cleanroom conditions.

The product

A crystal clear COC vial with a TPE closure.

The challenge

Fully automated production, assembly and closing of the container in a cleanroom to ensure internal sterility without post-mould cleaning.

The solution

KraussMaffei partnered with Rexam to implement highly automated cleanroom production of container and closure using KraussMaffei machines and robot systems. The two-platen CX machines with their cantilevered clamps are the key to separating the production and maintenance zones and to ensuring vertical laminar air flow through the clamp unit.

Only the clamp protrudes into the Class 5 cleanroom. Plasticizing and most of the pump and hydraulic units are outside. The machines can be run out of the cleanroom on tracks for maintenance work.

The benefits


Efficient production of a ready-to-fill aseptic container for the pharmaceuticals industry. Ease of use and no breakage risk. The new product has been welcomed by healthcare professionals.

The outcome

The KraussMaffei solution reduces the area of the Class 5 cleanroom, keeping costs to a minimum. By eliminating potential sources of dust and waste heat in the cleanroom area, it ensures ongoing compliance with high cleanroom classes. Although the risk of bacterial contamination in the vial is extremely low, post-mould gamma sterilization is performed to comply with sterility standards. The vials leave the cleanroom closed and packed. Vial filling costs are substantially lower, giving Rexam customers a competitive edge. KraussMaffei has a very successful track record for implementing this type of cleanroom production cell.



Intelligent production planning and the use of two-platen injection moulding machines makes it possible to comply with cleanroom standards up to Class 5 (DIN EN ISO 14644-1).

A middle-aged man with grey hair, wearing a white lab coat over a blue shirt and tie, is smiling warmly at the camera. He is sitting at a light blue desk in what appears to be a pharmacy or medical office. In his left hand, he holds a white and blue patient information leaflet. The background is slightly blurred, showing shelves with various bottles and a framed certificate on the wall.

**Developing effective, premium quality products
can be expensive – it's essential to protect this
investment.**



KraussMaffei cleanroom production systems guarantee consistent product quality and can include solutions to combat brand piracy. Because patients'

health can depend on the use of original products rather than counterfeits manufactured to lower standards.



CUSTOMER:

Gerresheimer Wilden

PRODUCT:

Screw cap for medical applications

FEATURES:

Compound with laser-detectable colour pigments as proof of origin

CUSTOMER BENEFITS:

Innovative integrated proof of origin for small bulk products

REAL-LIFE SOLUTIONS

Screw cap for Gerresheimer Wilden with integrated proof of origin

The background

Gerresheimer Wilden contacted KraussMaffei looking to implement a smart closure with integrated proof of origin for critical medication. The company has built a reputation with the excellent quality of its packaging and other products. It's in the company's interest to make sure counterfeit products are clearly recognizable, however, a solution using RFID chips is uneconomic for bulk products like caps.

The product

PP screw cap for syringe systems, integrating pigments that can be detected by a laser device.

The challenge

The manufacturer's proof of origin had to be fully integrated in the cap and reliably detectable using the special laser device. The cost of the solution had to be acceptable for bulk products such as medical consumer articles.

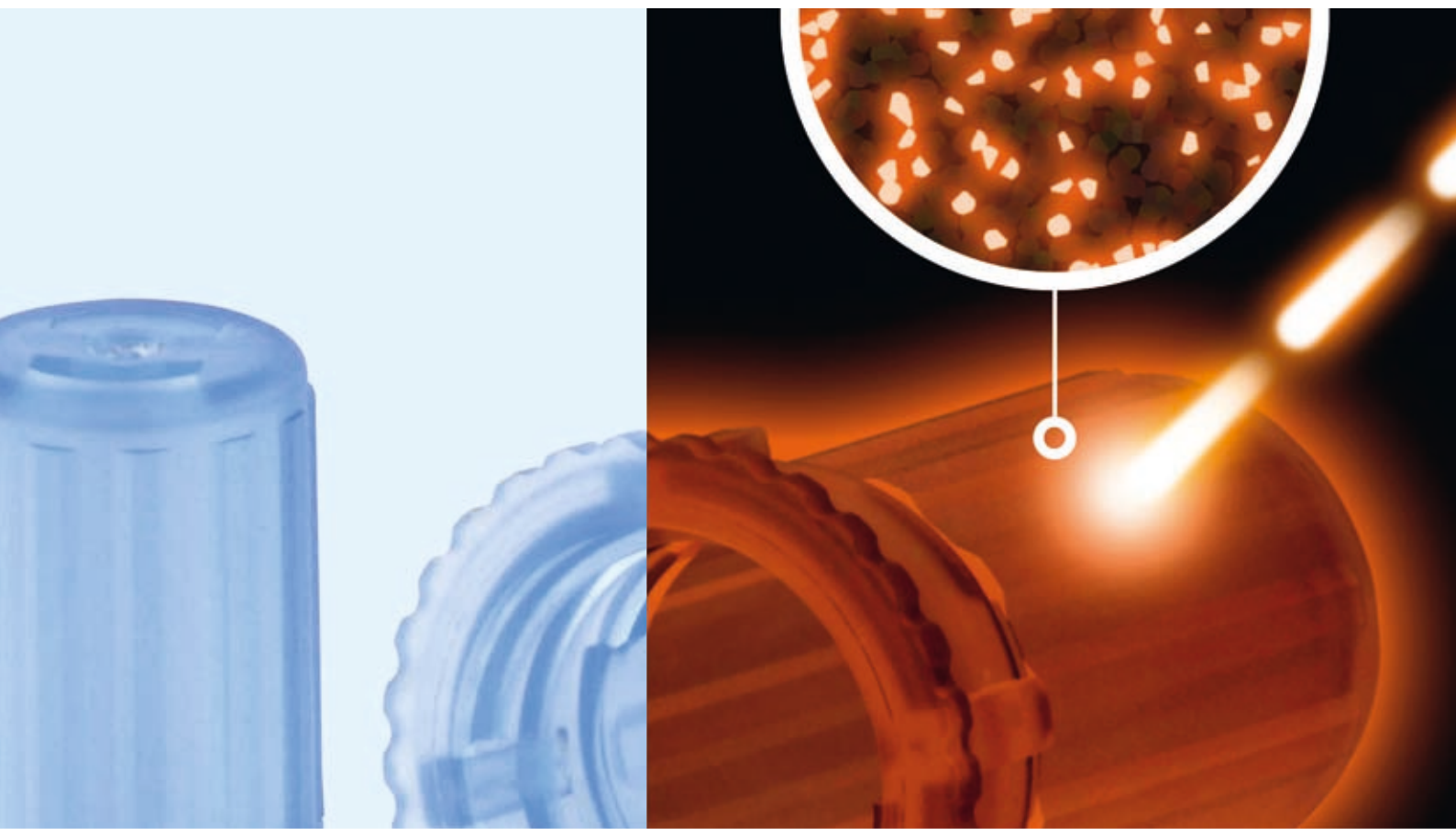
The solution

Together with 3M – a technology leader in security applications – and KraussMaffei, Gerresheimer Wilden implemented a new concealed security

solution for the cap. An existing IR pigment from 3M was added to an approved original material. KraussMaffei configured a twin-screw extruder to mix the required minimum amount of IR pigment evenly into the PP. The compound was then injection moulded – also in KraussMaffei machines – to produce the caps. Quality monitoring was integrated with the production cell in the shape of an automated detection unit to check the pigment in the finished caps.

The result

A cost-competitive method of adding concealed product authenticity features was the result. It is a realistic alternative, capable of protecting even bulk items from product piracy. Unambiguous proof of origin, integrated in the product by Gerresheimer Wilden, helps the company and its partners reap the advantages of their investment to make cutting-edge products.



“Intelligent components with integrated proof of origin are part of the technical entry barriers we will be using as protection against counterfeiting. This is important to us, because Gerresheimer Wilden has become market leader in the segments where it operates, thanks to its ability to supply complete solutions – from product development to ready-to-sell products with CE conformity. KraussMaffei is an interesting partner for us, because the company’s comprehensive product range – from compounding systems to injection moulding machines – meets a wide range of production challenges.”

Armin Henning, Managing Director International Production
Medical Plastic Systems

Service, support and spare parts – when you need them, where you need them



All-round service

Choose the service and support solutions that are right for your business. We'll configure your system, install and commission it, train your staff, advise on minimizing downtime and maximizing productivity, and carry out maintenance, repairs and upgrades.

Hands-on training for operators and service technicians

We'll train your operators and technicians in our Training Centres or on your premises anywhere in the world. Our graded course programme covers machine operation, process control and maintenance. We'll also organize special courses on customer-specific topics.



Talk to us, we're here to help you

Talk to us about your project. You can call on our expertise and experience from the start. We'll partner with you to find the optimal solution for your business.

Contact

Service hotline

Phone: +49 89 8899-3300

Fax: +49 89 8899-153300

Or write to us

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80997 Munich
Germany

KraussMaffei is a premium partner for the plastics and rubber processing industries worldwide. KraussMaffei machines and systems are used wherever plastics and rubber are converted into products. As a knowledge-driven technology company, we build on many decades of experience and a strong commitment to research and development.

Plastic products for the medical technology and pharmaceuticals sectors must meet rigorous standards and comply with legal requirements. Manufacturing them successfully takes a high level of specialized know-how. Product cleanliness and quality are critical. KraussMaffei has many years of sector-specific experience. Our system solutions meet all the criteria for high cleanroom classes. We are the only company in the world with comprehensive expertise in injection moulding, extrusion and reaction processing – the three primary methods for processing plastics and rubber. For companies in the life sciences sector, KraussMaffei is a competent partner for the entire value adding chain – from raw material to end product.

KraussMaffei Technologies GmbH

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