

WIRTHWEIN
MEDICAL

Forming Innovation.



IN PURE **FORM** FOR MEDICAL,
DIAGNOSTICS & PHARMA

english

COMPLETE SOLUTIONS MADE IN CLEAN ROOMS

All in one by Wirthwein

Founded in 1946, Wirthwein Medical GmbH & Co. KG is today a high-performance system supplier in plastics processing and a development partner for plastic-based and customer-specific product solutions. Focusing on quality and innovation, Wirthwein Medical has also internationally made its mark in the diagnostics, medical technology, pharmaceuticals industries – with high-precision, components, packaging and systems. In addition, proprietary products in the pharmaceutical sector complement the product portfolio.

Our core competences include development, design, mold making, injection molding and extrusion blow molding and a wide range of assembly, finishing and logistics services. Most of production is carried through in class 7 clean rooms pursuant to ISO 14644-1.

Highest, standardized quality and hygiene standards are assured using gapless, certified quality management according to DIN EN ISO 13485, 9001, 15378, 14001 and ISO 50001.

Presently, more than 330 employees work at three sites in Mühlthal and Ober-Ramstadt – on a total area of around 55,000 square meters.

A Wirthwein-Group company

Since 2005, Wirthwein Medical GmbH & Co. KG has been a subsidiary of the internationally active, family-run Wirthwein Group. With 22 companies in Europe, Asia and the USA the Wirthwein-Group is always in close proximity to its customers. More than 3,000 employees work in the business areas of Mobility, Rail Infrastructure, New Energy, Home Appliance, Medical and Interior Design.





A POWERFUL TEAM READY FOR YOUR CHALLENGES:

WE BRING PLASTICS TO LIFE

EXCHANGE OF EXPERIENCE ACROSS THE WIRTHWEIN-GROUP:

75 YEARS

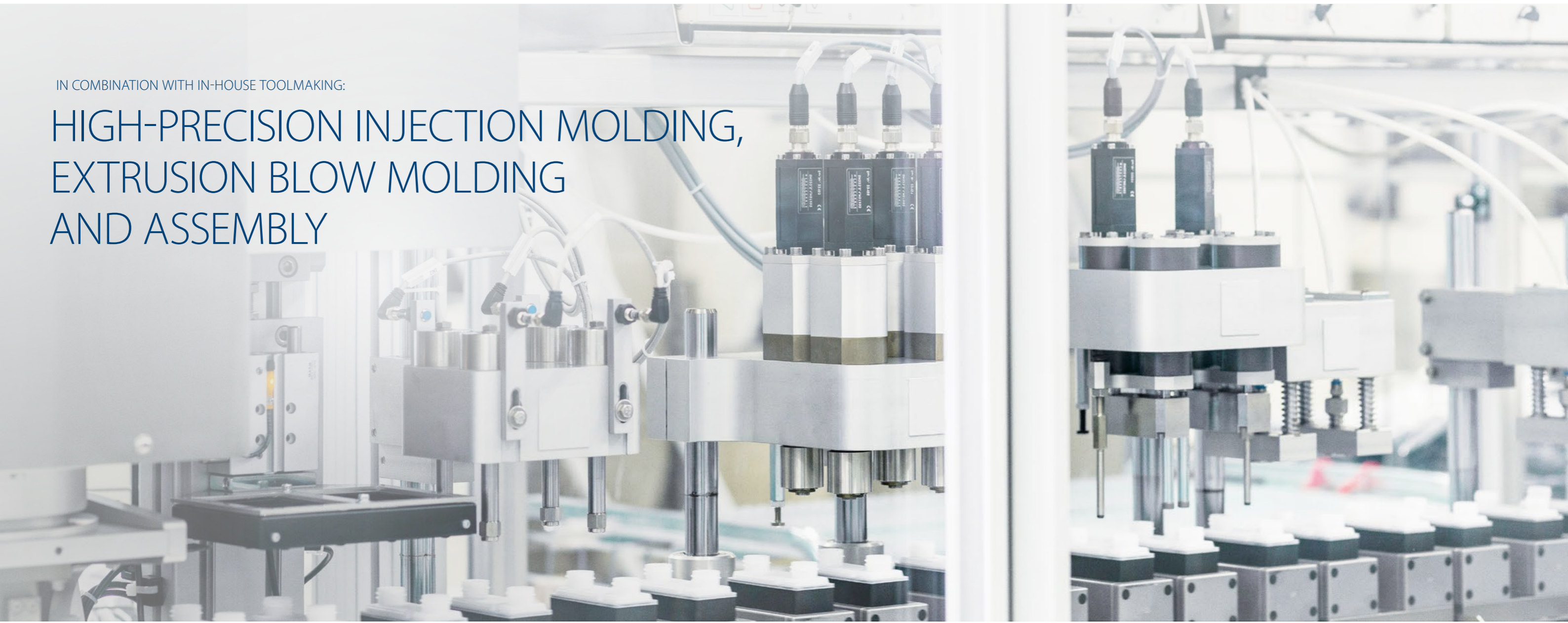
OF PASSION FOR PLASTICS PROCESSING

It is a key element of our daily work to satisfy customer needs to optimize specific needs in medical technology. Together with our customers and partners we rise to the challenges every day and face up to the responsibility for the health of millions of patients around the world.

Our products in combination with the services, experience and ideas of our highly qualified employees help us to cope with these requirements. By continuously optimizing work processes, quality and efficiency, we have developed ourselves into an innovative quality leader and a dynamic market leader in plastics processing.

IN COMBINATION WITH IN-HOUSE TOOLMAKING:

HIGH-PRECISION INJECTION MOLDING, EXTRUSION BLOW MOLDING AND ASSEMBLY



Clean room production and thermoplastic processing

By combining state-of-the-art injection molding and extrusion blow molding with our skills in toolmaking and assembly, we ensure efficiency and effectiveness in the production of complex plastic components. Integrated in a closed process at three sites we process more than 300 thermoplastics on a total of 100 injection molding machines and 15 extrusion blow molding machines. We offer all process steps from a single source, from prototyping to

series production. With a great wealth of experience in clean room production we produce system solutions and assemblies under standardized and controlled conditions.

We assemble and print customer-specific products on 35 state-of-the-art assembly machines, which we check 100% online using various inspection technologies in a fully automated process.

WE PRODUCE

2 BILLION

OF PLASTIC SYSTEMS EVERY YEAR

MORE THAN

4,000m²

OF CLEAN ROOM AREA



High-performance plastics for special challenges

The requirements to medical plastic systems and assemblies are becoming increasingly complex. Trends towards ever smaller molded parts and new material solutions, such as glass replacement by plastics, require a basic understanding of market demands and a consequent implementation of quality standards along the entire

value chain. As a system supplier for plastics processing in the medical technology industry we bundle all competences from development and design to clean room production, assembly, packaging and sterilization. Logistics services round off our portfolio as a full service supplier.

OUR COMMITMENT TO QUALITY:

100%

FOR THE
RIGHT
DIAGNOSIS



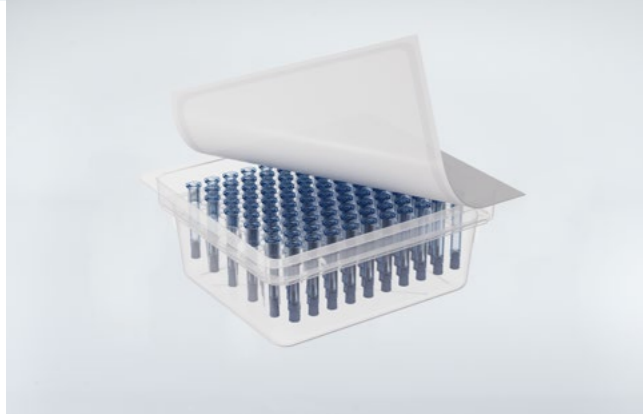
An accurate diagnosis saves lives –
our drive for the benefit of patients

Innovative diagnostic products ensure that patients around the world are given the right diagnosis concerning their individual health data which helps to increase their quality of life. The latest trends and developments in the fields of point-of-care diagnosis systems, microfluidics and increasingly smaller dispos-

ables require great experience and know-how along the entire manufacturing process. As a competent partner we design and manufacture components in the fields of blood, laboratory, PCR and point-of-care diagnosis systems under controlled clean room conditions.

100

STERILE SYRINGES PER TUB/NEST -
READY FOR FILLING



Highest quality and patient safety

Sterile prefillable syringes offer advantages in product safety, efficient logistics and production processes in the cosmetic and pharmaceutical industry. This supports the production of high-quality and safe injections for patients worldwide.

Our WIM Ject® syringe system is a high-quality, sterile, COC (cyclo-olefin copolymer) prefillable syringe and is suitable for a wide range of applications. The Tub/Nest packaged syringe system is complemented by individual backstop and plunger rod solutions.

150

MACHINES MANUFACTURE
ACCORDING TO YOUR IDEAS



Customized packaging solutions made of plastics

In several hundreds of projects and more than 75 years of company history we have mass-produced several billions of packaging solutions, closures, as well as application and mixing systems made of plastics. We offer premium quality and economical primary and secondary packaging material for a wide range of use in the

diagnostics, medical technology, cosmetics, pharmaceutical and food industries. By combining injection molding and extrusion blow molding technologies and by applying numerous assembly techniques we transform design concepts into functional packaging solutions.

UNCOMPROMISING QUALITY

FOR SPECIFIC REQUIREMENTS



Approvals, certifications and testing

Reliable, safe products and innovative developments are the result of consistent quality orientation. Ensuring and optimizing it along the entire process chain is a key element of the Wirthwein Medical quality management. Based on a certified, integrated management system, we meet our customers' requirements, the regulatory requirements for our clean room processes and the requirements for a sustainable, resource-friendly production.

- ISO 13485, 9001, 15378, 10001, 14001, 50001
- Class 7 clean room production pursuant to ISO 14644-1
- GMP requirements (Good Manufacturing Practice)
- We also take into account elements from the regulations and standards 21 CFR 820 Quality System Relations (Medical Devices), ISO 14001 and IATF 16949.



YOUR PROJECT WITH WIRTHWEIN MEDICAL

Do you wish to make an inquiry or would you like to talk to a competent contact person with industry experience for specific projects? Then please get in touch with us. We will gladly advise you.

Please make use of the contact form on our website, write us an e-mail or just call us.

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Since 1946 your reliable development partner and system supplier

- Uncompromising quality
- Globally active family enterprise
- Additive manufacturing and prototype development
- Production capacities for several million parts every year
- Clean room production (ISO class 7): several clean rooms
- Certifications: ISO 13485, 9001, 15378, 10001, 14001, 50001,
- In-house tool construction & maintenance: flexible, fast, high availability
- Injection molding, extrusion blow molding, assembly, packaging, and sterilization: all-in-one by Wirthwein Medical



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