CLEAN-ROOM TECHNOLOGY

Clean solutions, clean production
CLEAN RUNNING

Ideal combination: flexible injection moulding technology and multifaceted clean-room concepts.
Automotive, optics, microelectronics and of course medical – the scope of industries in which high-quality, clean production is required is wide-ranging. In order to achieve cost-effective production and consistently verifiable quality, you need the right concept for the task at hand. Our multi-disciplinary team of clean-room specialists ensures that even unusual solutions can be implemented for you. You can count on us!

WIR SIND DA.
If you wish to use the many opportunities now offered by clean-room production, you need the appropriate solutions. We have them – ranging in shape from flexibly adaptable injection moulding machines all the way to customised turnkey systems. You can rely on us as a technology and system partner. Several thousand ALLROUNDERs are working today reliably in a variety of applications under clean-room production conditions. That speaks for itself – and for us as well!

**Highlights**
- Several clean-room concepts
- Flexible expansion for optimal cleaning conditions (ISO 5)
- Automation and complete turnkey systems
- Versatile team of clean-room specialists
Realise requirements perfectly
For medical as well as technical applications, we implement precisely adapted clean-room solutions for you. Our modular product range offers a broad selection of series and sizes, different complementary clean-room concepts with tailor-made equipment packages and flexible expansion options. As a technology and system partner, we assume the planning and implementation of your complex production tasks. It cannot get more customised than that.

Minimising emissions on a targeted basis
You require a clean production environment to manufacture at high quality? The basis for that is our low-emissions, standard machine technology, such as liquid-cooled drives and control cabinets, combined with numerous equipment features for meeting the most stringent cleanliness requirements. This includes, for example, clean-air modules with ionisation for a high level of air circulation or stainless-steel covers for optimal cleaning conditions. It can hardly get cleaner than that.

Clean: our clean-room concepts prevent the contamination of moulded parts effectively.

Profit-oriented: our high-end technology reduces emissions and cycle times.

In-depth consultation
Clean-room concepts can only be as good as the expertise that lies behind them. Comprehensive consultation on machine and process technology is provided as a matter of course by us just as assistance with moulded part design and mould design. As a primary contractor, we cooperate closely with leading manufacturers of automation and clean-room technology. At our company headquarters in Lossburg, Germany, you can make use of a perfectly equipped clean-room laboratory. It could hardly be better.
CLEANLINESS: VERY SPECIFIC

Must special standards and guidelines be observed for your medical clean-room applications? Do your own quality specifications make a technically clean production environment necessary? For both cases, we are the right partner for you. That is because our extensive experience and perfect injection moulding technology enable us to meet every conceivable requirement, so that you can manufacture with high volume smoothly, reliably and, above all, cleanly.
Medical application

Biocompatibility, sterilisability as well as chemical resistance – these advantages make plastics an essential material in the field of medical technology. This means there is a wide range of applications, ranging from mass volume or disposable items and instruments to implants. For the success of a product, it is not just production under clean conditions (standardised freedom from particles and germs) that is decisive. Other important factors include the precision and reliability of the injection moulding machine that produces the parts to the highest quality standards.

Technical application

Whether lenses, sensors or decorative components with in-mould foils as well as downstream finishing by painting or chroming: the inclusion of particles often leads to a visible loss in quality. High requirements for cleanliness also prevail for micro-injection moulding, because the inclusion of particles would lead to malfunction here. An appropriate machine and clean-room concept is not only important for the necessary absence of particles in the production area. An individual quality assurance is also essential.
Clean-room conditions:

ISO 7 and ISO 8 are usual for injection moulding production; up to ISO 5 is possible for high requirements.

According to schedule: cleaning according to precisely defined intervals.

### CLASS MAXIMUM VALUE FOR PARTICLES PER m³ OF AIR

<table>
<thead>
<tr>
<th>Class</th>
<th>EN ISO 14644</th>
<th>0.1 µm</th>
<th>0.2 µm</th>
<th>0.3 µm</th>
<th>0.5 µm</th>
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<th>5 µm</th>
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<tbody>
<tr>
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<tr>
<td>ISO 3</td>
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<td>237</td>
<td>102</td>
<td>35</td>
<td>8</td>
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<td>352</td>
<td>83</td>
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<td>ISO 5</td>
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<td>–</td>
<td>352,000</td>
<td>832,000</td>
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<td>–</td>
<td>3,520,000</td>
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<td>–</td>
<td>35,200,000</td>
<td>8,320,000</td>
<td>293,000</td>
</tr>
</tbody>
</table>
Standards and guidelines

Protect injection moulded parts from air-borne contamination such as dust particles, bacteria or viruses? For this purpose, negative influences arising during production need to be limited and prevented from coming into contact with the product. In practice, this can be achieved through high-quality ventilation and air conditioning for example. The central set of regulations for defining clean rooms is the EN ISO 14644 standard. This can be supplemented by further EN ISO, VDI and VDA standards, the specifications of the GMP (Good Manufacturing Practice), directives from the European Union and US FDA (Federal Drug Administration) as well as individual specifications and corporate standards.

Qualified and validated

We offer comprehensive qualification documentation for all ALLROUNDERs in order to meet the requirements for ISO 13485 and GMP. It encompasses standard machine configuration, operating manual, functions descriptions, maintenance intervals, cleaning instructions, spare parts lists, setup plans and circuit diagrams. The inspection log book as a certification for the machine capability can be included if necessary. In order to maintain the reproducibility of an injection moulding machine, you can close a service contract with us which ensures a regular qualified re-validation.

Essential: clean operation

Regular cleaning and disinfection of the clean room and all production facilities are essential if a clean production environment is to be maintained. We provide injection moulding technology that is easy to clean and that makes operation correspondingly efficient. In addition, specific hygiene measures for personnel are decisive as well. Special work clothing and working guidelines (cleaning procedures before and after working in the clean room) are required with no exceptions.
For us, perfect clean-room conditions start with injection moulding technology adapted precisely to your individual requirements. After all, your products can meet the highest quality requirements only if your production operates with low emissions. With the flexible equipment options of our ALLROUNDERS, you can precisely rule out contamination sources and create a clean production environment. Clean-room production without compromises – reliably with us from the start!
Broad range: various machine models and sizes can be employed for clean-room applications.

Individual configuration: the appropriate equipment for any requirement.
Low-emission basis

The high-quality standard equipment of our ALLROUNDERS combats contamination and emissions effectively. The abrasion- and scratch-resistant powder enamel coating can be cleaned well. Liquid-cooled drives and control cabinets prevent air turbulence and cause only a very low level of heat dissipation. Dispensing with belt drives prevents particle contamination due to abrasion.

Ionised clean air

Clean-air modules draw in ambient air and produce clean air via a pre-filter as well as a high-efficiency particulate air filter (HEPA H14). The integrated ionisation system neutralises electrostatic charging, thus significantly reducing the number of particles on the moulded parts. The permanent air flow leads to a high level of air circulation in the working area. At the same time, air is displaced, effectively preventing the ingress of particles.

Clean-air module: Air circulation up to 500 TIMES PER HOUR

Close to the consumer: media connections on both the fixed and moving mounting platen.

Ionised: clean-air modules ensure low-particle air in the working area.
Flexible expansion

We offer a wide range of equipment features for a customised clean-room production. These include:

- raised machine feet for a clean production environment
- stainless steel sorter unit for the reliable separation of good and bad parts
- mobile clean-air module for quick, convenient changeover
- nickel-plated mounting platens with covered bores for the best cleaning conditions in terms of GMP A
- FDA/NSF H1-compliant lubricants

Further information:
Products and services brochure
CLEAN-ROOM CONCEPTS: MULTIFACETED

Thoroughly oriented to practical application – that is what our clean-room concepts are. This means that you decide which of our versions should be used in your production. That is because our design depends solely on your part and production requirements. The modular design of our entire technology enables simple application-specific adjustments – just as the addition of new features and functions.

<table>
<thead>
<tr>
<th>EQUIPMENT</th>
<th>CONNECTION TO CLEAN ROOM</th>
<th>PRODUCTION IN THE CLEAN ROOM</th>
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</thead>
<tbody>
<tr>
<td>Raised machine feet</td>
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<tr>
<td>Powder enamel coating „grey“</td>
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<tr>
<td>Extended conveyor belt with tunnel cover</td>
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<td>■</td>
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<tr>
<td>Stainless steel sorter unit</td>
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<tr>
<td>Media connections at the mounting platens</td>
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<tr>
<td>Mobile clean-air module above clamping unit</td>
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<td>■</td>
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<tr>
<td>Clean-air module above work area of robotic system</td>
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<td>■</td>
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<tr>
<td>Sealed safety enclosure for robotic system</td>
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<tr>
<td>Hydraulics cover</td>
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<tr>
<td>Cooling water manifold cover</td>
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<tr>
<td>Stainless-steel clamping unit</td>
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<tr>
<td>Nickel-coated mounting platens, covered bores</td>
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<tr>
<td>Lubricants with FDA and NSF H1 approval</td>
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<tr>
<td>Sliding guard with suction connection for injection nozzle tip</td>
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<tr>
<td>Inspection log book for the qualification and validation</td>
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</tbody>
</table>

■ Standard   □ Option
Connection to clean room

The ALLROUNDERs produce outside of the clean room – however, under clean conditions. This is ensured by clean-air modules above the working area. In addition to free-falling parts, an automated removal is also possible. It is also possible to feed in loaded parts from the clean room. Downstream operations such as quality control or packaging are carried out in the clean room itself. This design makes it possible to keep the clean room as small as possible. Machine and peripheral equipment do not burden the clean room with additional particles or heat. Additional benefit: Set-up processes become significantly easier.
Production in the clean room

Should production be under identical clean-room conditions? Then it is recommendable to set up the ALLROUNDERS in a clean room. Vertical and rotary table machines can also be integrated just as up- or downstream work processes. In this production environment, the machines and robotic systems are opened upwards in order to use the continuous ventilation within the production hall for generating air flow in the work area.

Individual clean-room cell

Sometimes the production tasks are so specific that a turnkey system is the most rational solution for you. As a technology and system partner, we assume overall responsibility and supply everything from a single source: from project planning to commissioning on your premises and training and system support. We cooperate closely with leading manufacturers of automation and clean-room technology. This means that high-quality production units are created precisely for your applications.
You want to ensure a smooth serial production of high-end injection moulded parts under clean production conditions? We offer the corresponding clean-room solutions – only first-rate: from the stand-alone machine to the fully automated turnkey system – all from an expert source. Either directly for your clean room, docked with the clean area or as an individual clean-room cell. Cutting-edge technology and in-depth expertise from ARBURG working hand-in-hand: That is clean-room production which leaves nothing to be desired.

APPLICATIONS: IN PRACTICE

- Injection compression moulding of optical lenses: dust-free atmosphere important for perfect quality.
- Producing medical drug implants: fully automated in clean-room classification ISO 5.
Bone pin: complex material gently prepared and processed according to utmost hygiene requirements.

Micro-fluid chip laboratories for diagnostics produce: GMP-compliant on stainless-steel ALLROUNDERS.

Inserts for blood flow diverters: safe overmoulding in docked-on production cell.

Particle-free in-mould lamination of display foils: individual turnkey solution from a single source.

Further information: Turnkey projects brochure