

# STRAIGHT INTO THE CLEANROOM!

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Development and production of  
cleanroom suitable products and  
assemblies such as clamping,  
gripping and handling technology

A PRACTICAL GUIDE



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# BASICS OF THE CLEANROOM

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## CLEANROOMS – FOR WHAT, FOR WHOM AND HOW?

Cleanrooms are needed for production processes in which structures in the micro- and nanometer range are created or where materials in these orders of magnitude are worked with. The size of airborne particles (dusts, microbes) and of individual undesirable gas and liquid molecules (AMC\*) are in the same range, namely below 5  $\mu\text{m}$ . They would therefore disrupt such processes, and in the worst case even destroy the products.

Cleanroom production used to be the domain of microelectronics and the pharmaceutical industry. In the meantime, however, microelectronics and nanoelectronics are penetrating all areas of technology. Nanotechnologies are also increasingly being used in materials and process engineering.

In the interest of product quality, this means that cleanroom production has now found its way into areas such as precision mechanics, optics, medical technology and even automotive engineering. Here, it affects the finishing of sensitive products and the assembly of corresponding subassemblies.

## Room in the room

The cleanroom is a specially constructed, functional room in the production area, hermetically sealed off from the environment by means of airlocks – usually separate for people and materials. A cleanroom of a higher class is always preceded by one of a lower class, or at least by something called the common cleanroom. It forms the transition to the normal environment.

## What should be clean must be clean

The building structure of the cleanroom and everything that is to enter it must comply with the desired degree of cleanliness: raw materials, components, tools, furniture and other supplies. All items are only allowed inside in special double packaging. The first packaging is removed in the common cleanroom, the second in the cleanroom.

Humans may enter cleanrooms only in suitable protective clothing. As biological beings, they pose the highest risk of contamination of all. Humans are therefore not allowed to enter a cleanroom of the highest class. Here, only manipulators and robots can be used.

*"Cleanroom" is the term used to describe a room that has an extremely low concentration of airborne particles. Airborne particles are all particles and substances suspended in the air, most of which cannot even be seen with the naked eye. Such cleanrooms are needed wherever particles present in the ambient air would interfere with the work."*

*Kathrin Schäfer: What is a cleanroom?  
Devicemed.de, 3.12.2018*

## MAIN FEATURES OF A CLEANROOM

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- Indoor room hermetically sealed off from the environment with airlocks
  - Slight overpressure inside with permanent aeration and deaeration, usually as a laminar flow\*
  - Alternatively: Vacuum (highest class cleanrooms)
  - Permanently operating air filters (HEPA\* and ULPA\* particulate filters for dust and microbes, chemisorption filters\* for AMC)
  - Permanently operating particle measurement technology; setting of constant air temperature and humidity in the interest of exact measuring conditions
  - Cleanroom suitable walls, ceilings, floors, lighting fixtures, furniture and work equipment
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\*) For explanations, see Cleanroom ABCs on p. 34

# NOT ROOM, BUT ROOM CONCEPT

Even more than architecture, a cleanroom is a working concept. Only by means of meticulously observed procedures in production and cleaning does its effect unfold. The conceptual backbone is the division of cleanrooms into classes.

## Standardized across industries

The classification of cleanrooms is standardized internationally. For the production of food, cosmetics and pharmaceuticals, the EU GMP\* guidelines apply. For everything else, and thus also for the majority of mechanical and plant engineering, EN ISO 14644-1 and -2 apply. The implementing regulation for the latter in Germany is the very detailed VDI 2083 Sheet 1. With two exceptions: In the semiconductor industry, the ITRS\* industry code of practice governs application practice; in the aerospace industry, ECSS-Q-ST-70-01 governs application practice. However, when it comes to cleanroom practices in detail, almost every company, whether it is a plant manufacturer or plant operator, has developed its own plant standards that suppliers must comply with.

## GMP and ISO

GMP and ISO each form their own cleanroom class systems, derived from the sizes and quantities of airborne particles allowed for a given volume of air. Both standards have their historical origins in U.S. Federal Standard 209E, which calculates in cubic feet and gallons – which is why the particle counts in GMP and ISO, converted to cubic meters, are so noticeably "skewed." One of the most common cleanroom classes is ISO 7. It is roughly equivalent to GMP C. However, the bridges between the two standards are not official.



*Cleanroom according to ISO or GMP? It depends on what is being produced here*



## The upper and lower end

The smaller the ISO number, the higher the cleanroom class. The upper end of the requirements is therefore marked by classes ISO 4 to 1. They apply primarily to the production of semiconductors and sensor technology, but now also to optics. In this case, there are mostly vacuum cleanrooms that cannot be entered by humans.

From cleanroom class ISO 9 upward, the cleanroom transitions to the common cleanroom. Physically, it is exactly the same as a cleanroom, but the cleanroom concept is less stringent. Closely related to this is the concept of the technical cleanliness\* of components. The common cleanroom has its origins in the automotive industry. Other industries with comparable requirements follow suit.

## Cleanroom classes according to EN ISO 14644-1

Class	Maximum particle count per m <sup>3</sup>					
	≥ 0.1 µm	≥ 0.2 µm	≥ 0.3 µm	≥ 0.5 µm	≥ 1.0 µm	≥ 5.0 µm
ISO 1	10	–	–	–	–	–
ISO 2	100	24	10	–	–	–
ISO 3	1000	237	102	35	–	–
ISO 4	10000	2370	1020	352	83	–
ISO 5	100000	23700	10200	3520	832	–
ISO 6	1000000	237000	102000	35200	8320	293
ISO 7	–	–	–	352000	83200	2930
ISO 8	–	–	–	3520000	832000	29300
ISO 9	–	–	–	35200000	8320000	293000



# BASICS OF CLEANROOM SUITABLE MANUFACTURING

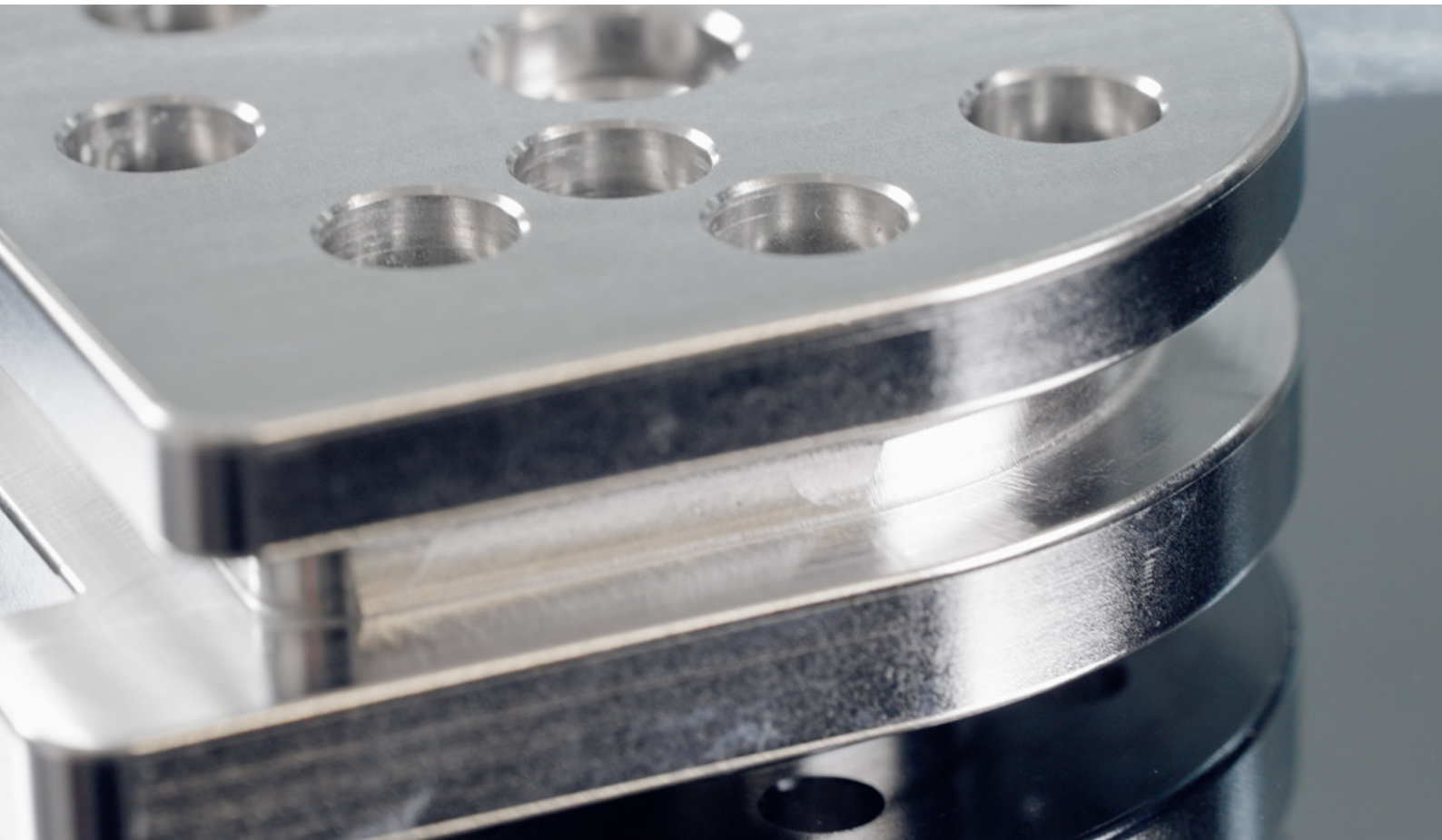
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# SPECIAL MATERIALS, SPECIALLY PROCESSED

Components or assemblies, in fact all operating equipment that is to be used in the cleanroom, must be designed and manufactured differently than conventional ones. The differences start with the choice of material and end with the surface quality.

The most important requirements for materials suitable for cleanrooms are: abrasion resistance, corrosion resistance, minimal electrical charge and minimal outgassing – here we are talking in particular about VOC\*. This severely limits the range of possible materials. Stainless steels form the main group. Corrosion resistance is mandatory to prevent the formation of corrosion products and thus loose particles. In addition, there are some

aluminum alloys and special plastics. Cadmium, magnesium and zinc, on the other hand, are not considered suitable for cleanrooms. Copper is prohibited, especially in the field of microelectronics and nanoelectronics, because it destroys the semiconductor properties.



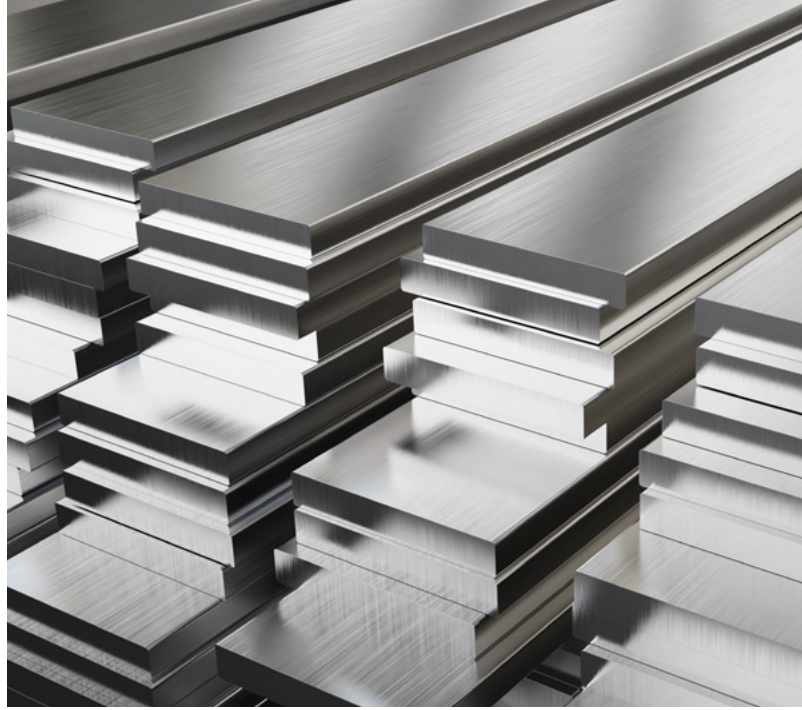
*Cleanroom suitable component for clamping, gripping and handling technology made of stainless steel. Typical: the rounded edges*

## Closed surfaces

Cleanroom suitable components or assemblies must be designed with more closed surfaces than conventional ones. Parting lines, beads, undercuts and cavities must be avoided. They all represent potential particle traps and make cleaning more difficult. For this reason, a monolithic design should also be given preference over assembly from individual parts.

## Vacuum suitability

The highest cleanroom classes are concerned with vacuum suitability. Here, absolute freedom from outgassing is required. This further restricts the range of materials and, in the case of the remaining materials, places the highest demands on production – in the case of steels, for example, on the melting method. In the case of components for use in a vacuum, moreover, blind holes must be provided with additional vent holes to allow complete evacuation.



*Stainless steels –  
the most important  
materials in the cleanroom*

## Low-abrasion joints, rounded edges

Apart from this, material pairings, such as screw connections, cause abrasion. If they cannot be avoided, they must be designed in such a way that abrasion is already reduced to an absolute minimum during assembly. For less stringent requirements, it is sufficient to silver-plate or gold-plate screws. However, if high forces are involved or if the screw connection is to be detachable, special steel with sliding properties must be used. Rounded edges are also important: They bind fewer microparticles, produce less abrasion themselves than sharp ones, and also interfere less with the air flow in the cleanroom – if there is any.

*Cleanroom suitable component of the clamping, gripping and handling technology. Combination of stainless steel and plastic, gold-plated threaded hole*



## Hardly any lubrication

Many components or assemblies have to perform movements. This also means friction pairing. Only special lubricants suitable for cleanrooms may be used, for example those based on perfluorinated polyether oils and PTFE ("Teflon"). In the highest cleanroom classes, lubricants are completely excluded. The friction pairing must therefore function dry. Unfortunately, stainless steels in particular tend to cold weld ("seize").

## Little movement

In the cleanroom, the design principle is therefore: any avoidable movement must be avoided. If movements cannot be avoided, they must be kept as small as possible and the materials and design must be such that there is as little abrasion as possible. If there is a choice between rotary and linear motion, preference should be given to rotary motion. Plastics with special sliding properties are used for the material pairing. Where this is not sufficient, appropriate special steels are used. All friction pairings must be encapsulated.

## Best surface

To prevent the deposition of microparticles on the one hand and to ensure the best cleanability on the other, components and assemblies suitable for cleanrooms must have smooth, closed surfaces. At the very least, they must be free of pores, scratches, grooves and dents. In most cases, however, they must also be polished and provided with sealing surface coatings.

## Practical guide

A practical guide to the complex requirements for cleanroom suitable materials, component surfaces and the associated quality testing is provided by the proposals of the CSM\* industry association. In the meantime, they have found their way into the draft of VDI Guideline 2083 sheets 9.1 and 17 (cleanliness suitability of equipment and air-conditioning components).

## REQUIREMENTS FOR CLEANROOM SUITABLE MATERIALS AND COMPONENTS ACCORDING TO CSM:

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- good abrasion resistance
  - good mechanical resistance
  - good chemical resistance
  - low outgassing
  - smooth, non-porous surface
  - good cleanability
  - high discharge capacity
  - resistance to disinfectants (medical technology)
  - biostatic or microbicidal effect (medical technology)
- 

Source: Fraunhofer IPA





# CLEANROOM- SUITABLE PRODUCTS FROM RÖHM

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*Cleanroom suitable components  
from RÖHM in the ultrasonic  
cleaning bath*

# CLAMPING, GRIPPING AND HANDLING TECHNOLOGY. FOR CLEANROOMS

For more than 110 years, RÖHM has been producing clamping, gripping and handling technology.

Many large machine and plant manufacturers worldwide list us as a standard supplier for drill chucks, lathe chucks, centers, robot gripping technology or clamping devices.

Together with the companies that it supplies, RÖHM has now entered the cleanroom.



*Cleanroom suitable component of clamping, gripping and handling technology made of plastic, with threaded holes made of special steel*

Our products are known for their exceptional combination of robustness, precision and intelligent force and motion control. This is particularly in demand in the cleanroom. More than in a normal production environment, the aim here is to reach the target safely with a minimum of movement and force.

## CLEANROOM SUITABLE PRODUCTS FOR CLAMPING, GRIPPING AND HANDLING TECHNOLOGY FROM RÖHM

- Swivel units
- Upgrade devices
- Retrofit devices
- Add-on modules
- Carrier frames
- Handling devices
- Handling frames
- Transport carts
- Transport devices
- Buffer storage inserts
- Absorber plates
- Sealing plugs
- Clamping heads
- Holding fixtures (chucks)
- Support pins (pins)
- Mechanical assemblies

## EXPERIENCE WITH DIFFERENT INDUSTRIES



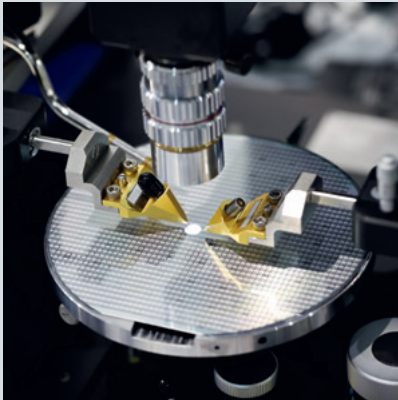
### OPTICS

Clamping for the finishing and installation of precision optical assemblies



### PRECISION MECHANICS

Clamping and gripping tools for the mechanical machining of housings for high-quality watches



### SEMICONDUCTOR MANUFACTURING

Mechanical assemblies for plant and process solutions



### MEDICAL TECHNOLOGY

Clamping tools for finishing of implants



# PROJECT PLANNING AND PROCESS FLOW

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# CLEAN PLANNING, CLEAN MANUFACTURING

Clamping, gripping and handling technology for the cleanroom is always about customer-specific products. RÖHM brings know-how both in cleanroom suitable production and in the actual cleanroom production.

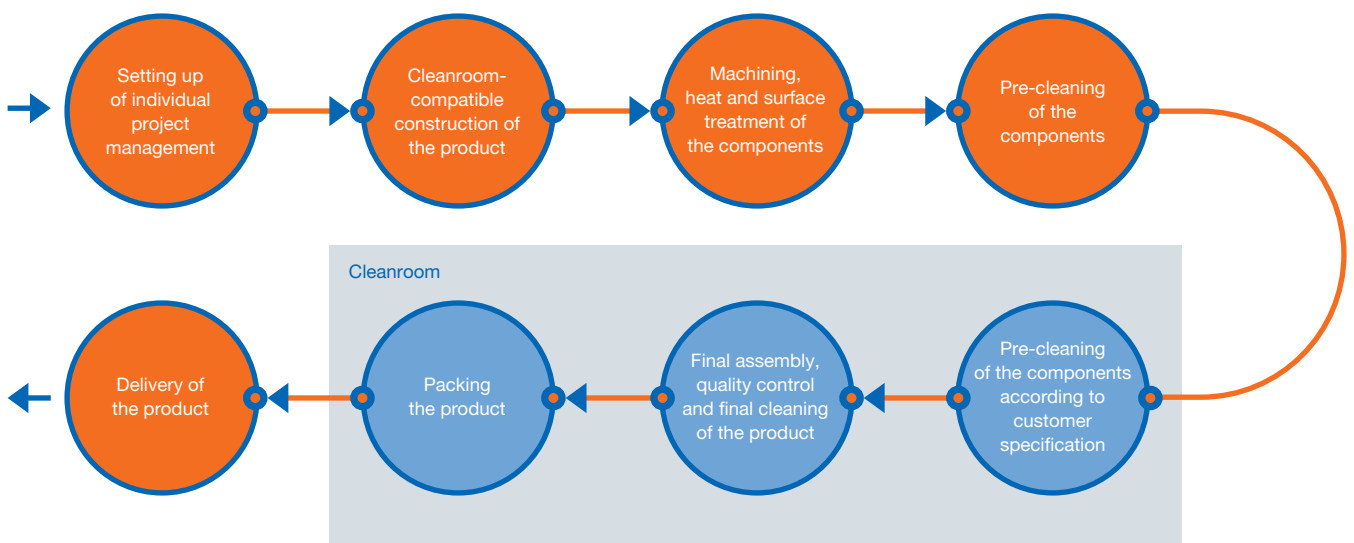
First of all, individual process management is set-up for each project together with the customer – depending on the specific task and the targeted cleanroom class. On request, RÖHM will take into account the specifications for materials and their processing as well as the selection of suppliers.

## Own cleanroom design

The cleanroom suitable design and the constructional design of the products are carried out by us. The results are coordinated with the customer via agreed intermediate steps. Upon request, RÖHM also manufactures according to drawings.

## Own cleanroom suitable production

For the production of cleanroom suitable products, RÖHM has developed a safe procedure based on experience. Most of the manufacturing steps are done in-house. Special individual steps, for example for heat treatment of steels or for preparation for the highest cleanroom classes, are carried out exclusively by proven suppliers.



### Own cleanroom production

If the product is to be used in a cleanroom class not higher than ISO 7, RÖHM subsequently carries out the finishing and assembly in the in-house cleanroom tent, if necessary. For higher cleanroom classes (< ISO 7), customer-specific agreements are made – including the selection of suitable suppliers for the crucial final steps of cleaning and packaging the products.



Assembly in the cleanroom tent from RÖHM

## THE CLEANROOM TENT FROM RÖHM

<b>Planning and setup</b>	MCRT, Heuchelheim
<b>Cleanroom class</b>	ISO 7
<b>Maximum manageable component volumes</b>	approx. 2 m <sup>3</sup>
<b>Maximum manageable component mass</b>	1,000 kg
<b>Upstream common cleanroom</b>	with material and personnel airlock, with cleaning baths for incoming and outgoing objects
<b>Other features</b>	ESD protection floor, darkroom with particle measuring technology







# CLEANROOM MATERIALS AT RÖHM

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*Smooth, hard, and corrosion-resistant – materials are only cleanroom suitable if they allow the setting of maximum surface quality*



# NARROW PALLET, CERTIFIED ORIGIN

The range of cleanroom materials regularly used by RÖHM is narrow. It is based on the high requirements of the optical industry, for example. This is partly about production in cleanroom classes below ISO 5, i.e. vacuum cleanrooms, but at least ISO 7.

The main construction materials are stainless steels. They are very different in the specification of their properties. The ideal steel does not exist. The selection must always be a balance between corrosion resistance, strength (including abrasion resistance), magnetization behavior (in the case of a tendency to attract particles) and processability. In addition, there may be a requirement for vacuum-compatibility.

## At least surface hard

Austenitic (non-magnetic) steels are mainly used. They usually have good corrosion resistance, but are relatively soft and therefore often need to be surface hardened or coated to achieve cleanroom compatibility. Examples are the steels 1.4301 or 1.4404. If the focus is on high-strength requirements over the entire component cross-section, the naturally hard duplex steel 1.4462 or tool steel 1.4112 is used. However, this is also used in the naturally hard state, because conventional hardening would inadmissibly increase the corrosion tendency in terms of cleanroom compatibility. For vacuum requirements, maraging 1.4548 is suitable (aviation approval). This means that the magnetization behavior and machinability of the material are compromised.

## Highest metallurgical grade

All steels come from manufacturers offering the highest metallurgical grade. In the interests of vacuum compatibility, for example, they have to remelt the steels to minimize the risk of outgassing right from the start.

For friction pairings with the highest requirements – threaded sleeves and plain bearings – Nitronic 60, a special steel from the US manufacturer Armco with very good sliding properties, is used.

## Supplemental: Aluminum and plastic

For components subject to lower mechanical and thermal stresses and in a medium cleanroom class, two aluminum alloys are used in addition which, especially with an anodized surface, have very good cleanroom compatibility. This helps to relieve the construction. Special abrasion-free plastics are also used under similar operating conditions. This is especially the case with gentle handling or friction pairings, i.e. lubricant-free plain bearings. Only plastics from selected manufacturers are approved. PTFE or PEEK are often sufficient for minor to medium stresses. The plastics of the Iglidur family from the manufacturer Igus occupy a special position due to their unique sliding properties even under higher mechanical stress. Where higher operating temperatures must also be expected, POM or the extremely resistant PBI come into play.



## ALUMINUM ALLOYS

- 7175
- AA5083



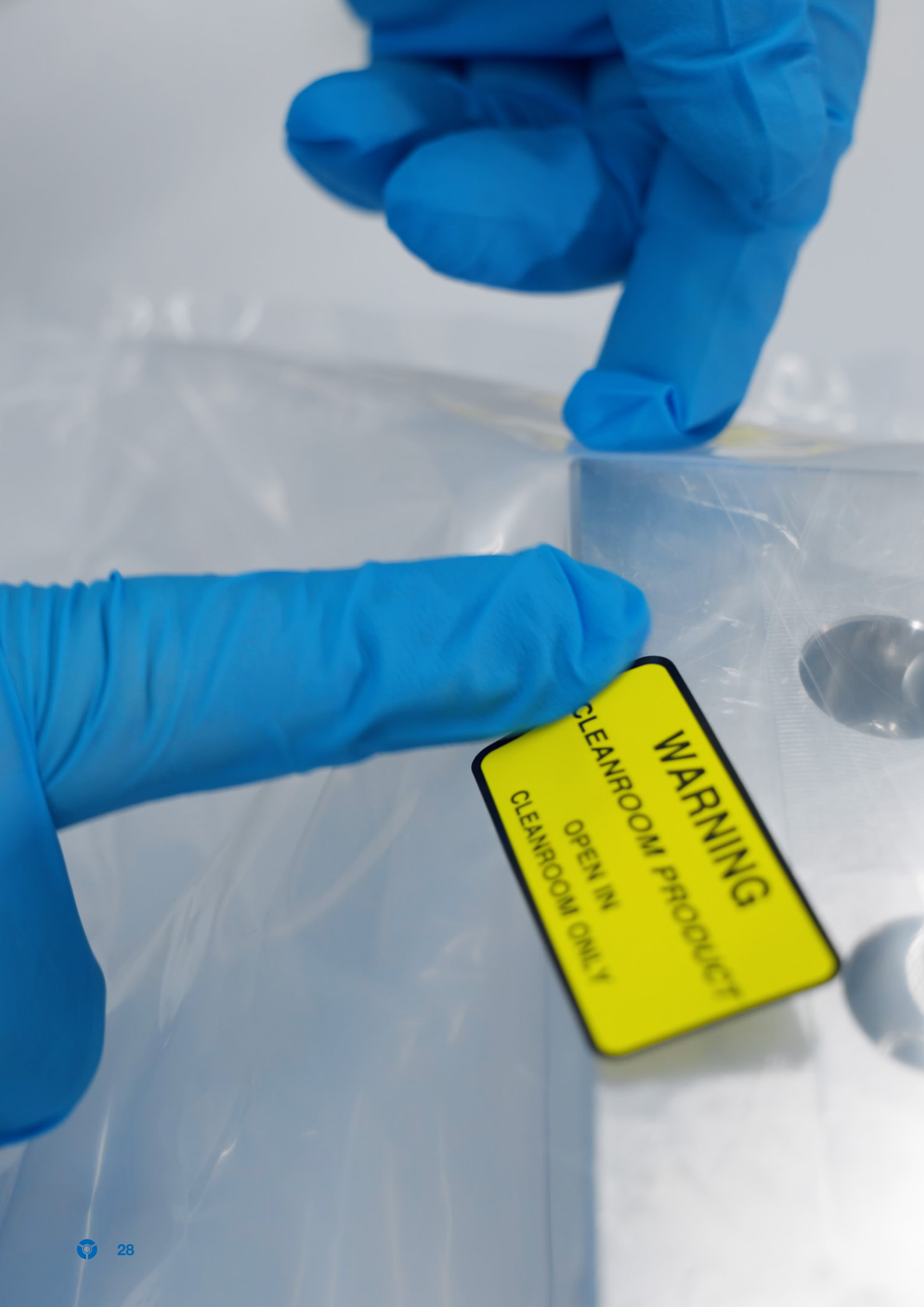
## STAINLESS STEELS

- 430F
- 316L
- UNS S32205 / F51, F60
- 17-4 PH
- 304
- 316Ti
- 440B
- 309ss / Alloy218



## SPECIAL PLASTIC

- Iglidur J and C
- Polyamide
- PBI
- PEEK
- POM
- PTFE, Teflon



**WARNING**  
**CLEANROOM PRODUCT**  
OPEN IN  
CLEANROOM ONLY

# PROCESS FLOW FOR THE MAIN MATERIAL STAINLESS STEEL

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# FROM THE SAW TO THE CLEANROOM IN TWO VERSIONS

Cleanroom suitable production at RÖHM is determined by the process sequence of machining stainless steels. Two versions can be distinguished. Basic production is basically the same in both cases; the differences become apparent in finishing.

## Three surface finishes

Only three final surface finishes for stainless steel in the cleanroom are permitted at RÖHM: DLC coated\* (finishing version 1) or passivated\* or electropolished\* (finishing version 2).

## Sawing

Stainless steel comes off the shelf, so it must first be sawn to length. In order to avoid cross-contamination between the materials, which would impair corrosion resistance, the saws used for this purpose are reserved exclusively for cleanroom steels. Saw blades are used exclusively for one and the same steel grade.

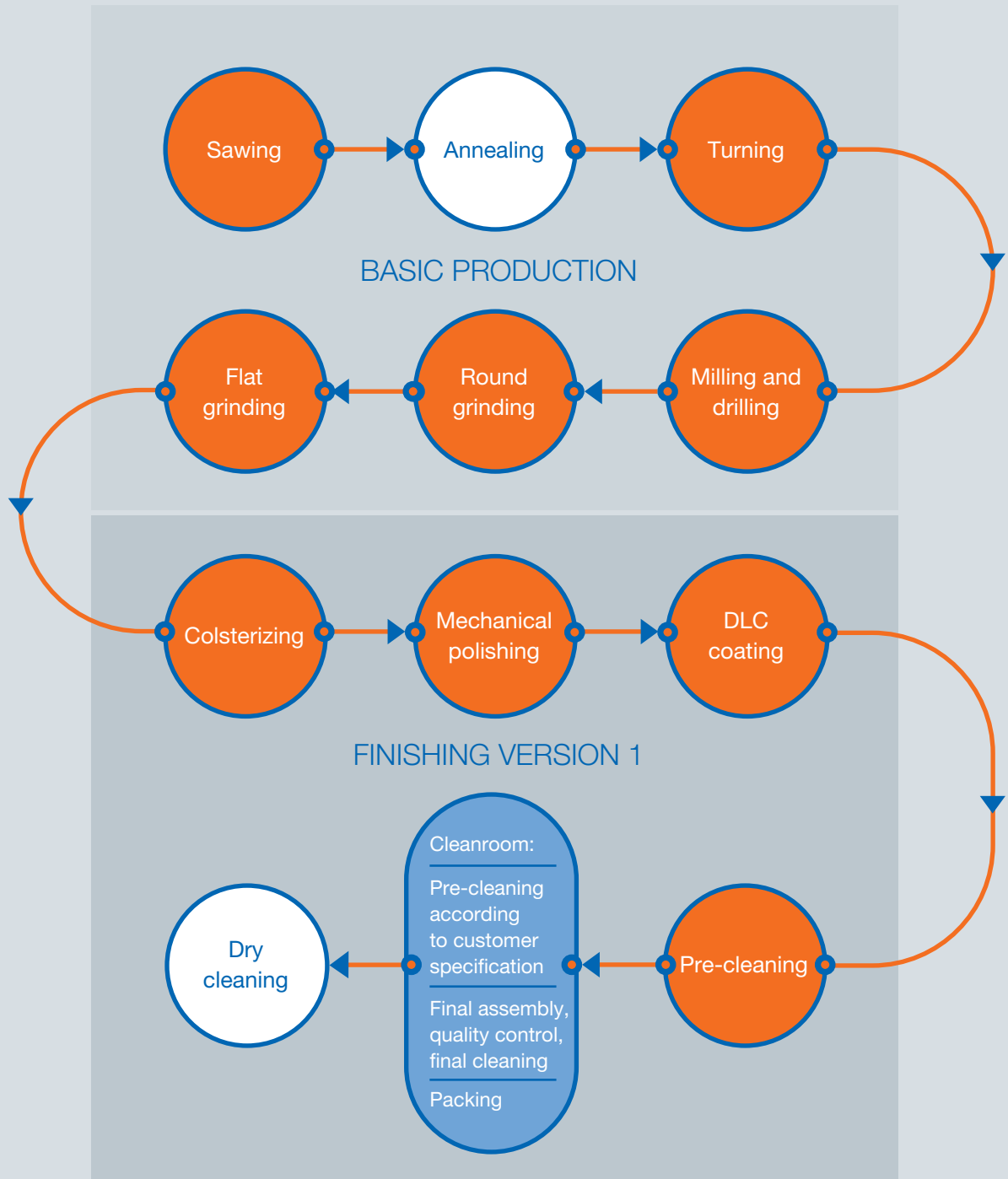
## Annealing

To better prepare the steels for fine machining (turning, milling, drilling and grinding), some of them are annealed after sawing. The martensitic steels 1.4104 and 1.4112 are soft annealed. The austenitic steels 1.4404 and 1.4571 are stress-relief annealed only at low temperatures, as is the duplex steel 1.4462. The other steels are not annealed.

## Turning, milling, drilling and grinding

The rules for avoiding cross-contamination already mentioned under "Sawing" also apply to fine machining. The greatest care and meticulousness is required during machining and handling in order to achieve the surface quality specifications already mentioned above. High-gloss milling\* results in particularly smooth surfaces. Gloves must be worn during the final stage of the process. Meticulous cleaning of the workpieces immediately after machining is mandatory.

MANUFACTURING PROCESS FOR  
STAINLESS STEEL, **VERSION 1**



## Colsterizing\*

Now the material surface must be brought to the final state that is optimal for cleanroom purposes. As a preliminary step, surface hardening is important first. The intention is to increase wear resistance, reduce the tendency to seize and, in the event of a subsequent hard coating, mediate between this and the relatively soft substrate. Classic surface hardening processes such as surface hardening or nitriding are not suitable: They would reduce the corrosion resistance in terms of cleanroom suitability too much – even with steels that are in principle suitable for this. Therefore, a special process is applied to all stainless steels used by RÖHM for cleanroom purposes: colsterizing. Outside such applications, it is mostly used only for austenitic steels. Colsterizing achieves the above objectives without increasing the risk of corrosion. The heat treatment is carried out by our partner company Bodycote.

## Either mechanical polishing and DLC coating\*

Version 1 of the following manufacturing process concerns applications with the highest cleanroom requirements. On the one hand, this involves vacuum suitability. On the other hand, it involves moving material pairings that require maximum wear resistance and minimum seizure. In both cases, colsterizing is followed by mechanical polishing and then the super-hard DLC coating. Polishing is important for the adhesion of the coating. A particularly gentle special process is used, which is carried out with a granulate of walnut shells works as a polishing agent.

## Or passivation and electropolishing respectively

If the mechanical requirements are less stringent, version 2 of the manufacturing process is continued after colsterizing: passivation or electropolishing. Both processes are related to each other. They create a thin, non-metallic and particularly corrosion-resistant protective layer on the steel.

This is necessary because even stainless steel without such a layer is not fully protected against corrosion. In addition, both processes additionally smooth the surface and remove loose inclusions from the steel surface – the final contribution to minimizing particle release. Electropolishing represents the more aggressive variant of passivation – it is therefore not always suitable for particularly delicate components.

## Wet cleaning and assembly in the cleanroom

The wet cleaning of the finished components and assemblies takes place in two steps in ultrasonic baths in the RÖHM cleanroom. In the first step, fully desalinated water (deionized water) is used, to which a special cleaning agent is added. In the second step – at approx. 50 °C for approx. five minutes – pure deionized water is used. The subsequent drying is done with IPA cloths. This means that the products are ready to enter the ISO 7 class cleanroom through the lock.

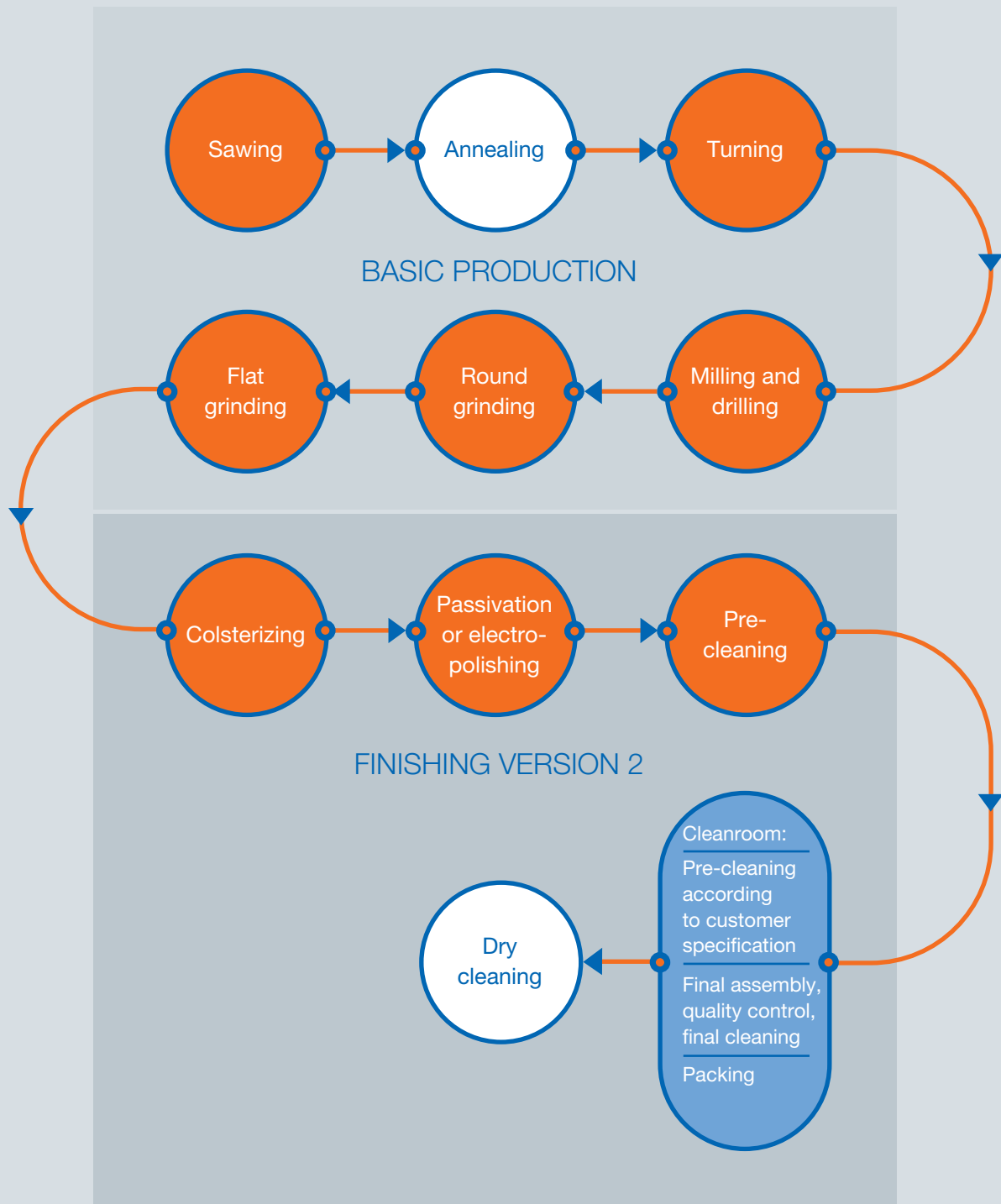
If assembly work still has to be carried out, it takes place there. Quality control of the finished products also takes place in the cleanroom. This is followed by final cleaning in the darkroom using particle measurement technology. After that, the products are finally packed and sent to the customer.

## Dry cleaning

If the products are to be further processed in a cleanroom of a higher class, in particular in a vacuum cleanroom, the wet cleaning is followed by dry cleaning. This is carried out by a specialized provider. For this purpose, the products are stored at higher temperatures for several hours or days in a vacuum – until the measured outgassing values have reached the required minimum. The parts are then sent directly to the customer for further processing in cleanroom suitable packaging.



MANUFACTURING PROCESS FOR  
STAINLESS STEEL, **VERSION 2**



# CLEANROOM ABCS

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<b>AMC</b>	"Airborne molecular contamination"; individual molecules of foreign contaminants); individual molecules of foreign gases and liquids in the cleanroom air
<b>Chemisorption filter</b>	Type of filter that separates molecules of gases and liquids (-> AMC, ->VOC) by means of adsorption involving "pseudochemical binding processes" on the filter medium surface (e.g. on activated carbon)
<b>CSM</b>	"Cleanroom Suitable Materials," industry alliance led by the Fraunhofer Institute for Manufacturing Engineering and Automation (IPA), Stuttgart. Develops test methods for cleanroom suitability of equipment and develops optimized products for this purpose
<b>DLC coating</b>	"Diamond-like carbon", thin film of amorphous carbon produced by vapor deposition, primarily on steel surfaces. Extremely hard, wear-resistant and slippery. Vacuum compatible
<b>Electropolishing</b>	Electrochemical removal process using an external current source. The workpiece forms the anode of an electrochemical cell. The electrolytes used include mixtures of phosphoric and sulfuric acid. Leads to an extremely smooth, particularly corrosion-resistant surface.
<b>GMP</b>	"Good Manufacturing Practice". The EU GMP guideline defines cleanroom classes in pharmaceutical, food and cosmetics manufacturing. The strictest regulations are defined in Annex 1. They apply to pharmaceuticals, drugs and active medical ingredients.
<b>HEPA filter</b>	"High-efficiency particulate air filter", particle filter, in the best class H14 with a minimum separation efficiency of 99.995% for particles from 0.1 to 0.3 µm diameter
<b>Mirror-finish milling</b>	Produces a mirror-like material surface by milling at ultra-high speeds without visible machining marks. Achieves a center roughness value of 0.0145 µm and a maximum roughness value of 0.025 µm
<b>ITRS</b>	The "International Technology Roadmap for Semiconductors" describes how to implement the specifications of ISO 14644 in semiconductor industry processes.
<b>Colsterization</b>	Special surface hardening process for stainless steels that retains its shape, color and dimensions; carried out below 500 °C and without quenching. In this process, large quantities of carbon atoms are deposited on interstitial sites of the crystal lattice on the surface of the steel through which it is distorted and strengthened. A classic hardness structure, on the other hand, does not develop. Registered trademark of Bodycote.

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<b>Laminar Flow</b>	Laminar flow; the most common artificially generated type of air flow in the cleanroom. Vertical air flow; the air is blown-in in the ceiling and extracted in the floor.
<b>Passivation</b>	Creation of a non-metallic corrosion-protection layer on a metallic surface by treatment with nitric or citric acid.
<b>Technical cleanliness</b>	A component is considered technically clean if the residual particles on it do not impair the correct functioning of the component or assembly. This test is described in ISO 16232 "Road vehicles – Cleanliness of components and systems" and – with practical relevance for Germany – in VDA Volume 19 "Testing of technical cleanliness; Particle contamination of functionally relevant automotive parts".
<b>ULPA filter</b>	"Ultra-low penetration air filter", particle filter, in the best class H17 with a minimum separation efficiency of 99.999995% for particles from 0.1 to 0.3 µm diameter
<b>VOC</b>	"Volatile organic compounds", e.g. ammonia, formaldehyde, hydrogen chloride or hydrogen sulfide, which affect the cleanroom atmosphere or the cleanroom vacuum, especially in the form of outgassing from solids; subform of -> AMC.



If you need cleanroom suitable clamping, gripping and handling technology: You will find the contact to us here. Something for the cleanroom never comes off the shelf. The previous pages have already shown you. You will quickly find out what RÖHM can do for your cleanroom project in a first conversation with us. Details to follow.

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