medical COMPONENTS
Your plastic CDMO

MEDICAL PLASTIC COMPONENTS CDMO

Your partner for high-quality plastic components and tailor made solutions

GRIFOLS

We care about your components **as if they were our own**

Grifols Medical Components CDMO specializes in the development and manufacturing of high-quality medical-grade components, grounded in the same rigor, precision and compliance that define Grifols as a global healthcare leader.

We are able to leverage the industrial expertise, supported by robust quality systems, advanced manufacturing technologies, resources and experiences of the larger Grifols organization to provide significant value to our partners.

We partner with healthcare companies seeking a trusted collaborator capable of polymer engineering, custom injection molding, welding, assembly, and end-to-end industrialization.

Our Murcia **facility**

Our large-scale facility, established in 2002, is designed for high-volume, high-quality manufacturing of medical plastic components, combining advanced manufacturing technologies with extensive cleanroom expertise.

Production site in Las Torres de Cotillas (Murcia, Spain):
17,300 m² (186,216 ft²)

Raw materials warehouse:
1,792 locations

SILO warehouse:
8,500 locations

All manufacturing takes place in Class C (ISO 7) cleanrooms:

- 15 **cleanrooms dedicated to plastics production**
- 35 **cleanrooms for finished products**
- 6 **steam sterilization autoclaves**

Manufacturing capabilities

Our integrated capabilities enable end-to-end manufacturing, from component production to final assembly and sterilization

Injection molding

- 15 injection molding machines (30–120 tons)
- Processing of PVC, PP, ABS, and other materials
- 90 molds for a wide range of components
- 250 million parts per year

Automated assembly

- 8 automatic assembly lines
- Assembly of various cap components
- 90 million parts per year

Packaging and sterilization

- Manual assembly line
- Customized kits sterilized via EtO or Gamma

PVC: polyvinyl chloride, PP: polypropylene, ABS: acrylonitrile butadiene styrene, EtO: ethylene oxide

Collaborating with Grifols

Partnering with Grifols means gaining a structured and reliable pathway from concept to industrialization. We support our customers across the full product lifecycle, from early concept definition to validated, large-scale manufacturing and supply.

Our Murcia facilities combine advanced automation, expertise in polymers and medical device engineering, together with pharmaceutical-grade validation, enabling a fully integrated and compliant path to market-ready solutions.

FROM CONCEPT TO INDUSTRIAL PRODUCTION

1 CONCEPT AND FEASIBILITY

- Evaluation of product idea and project feasibility
- Cross-functional assessment (R&D, Quality, Regulatory, Manufacturing)
- Definition of specifications, intended use, and project objectives

2 MATERIAL SELECTION AND DEVELOPMENT

- Selection of technically suitable medical-grade materials
- Supplier qualification to ensure compliant manufacturing
- Material testing and optimization based on performance and application needs

3 DESIGN AND ENGINEERING

- Component design adapted to injection molding, welding and assembly processes
- Design for manufacturability and process optimization
- Development of initial product concepts and manufacturing approach

4 PROTOTYPING AND PROCESS DEVELOPMENT

- Development of prototype and tooling with qualified partners
- Manufacturing of prototypes and pilot batches
- Sterilization process development by gamma radiation, ebeam and EtO

5 VALIDATION AND INDUSTRIALIZATION

- Design verification and validation of product and processes such as, IQ, OQ, PQ
- Shelf-life and ageing studies
- Transport simulation and packaging integrity testing
- Biocompatibility and regulatory compliance

6 ANALYTICAL AND MICROBIOLOGICAL CAPABILITIES

- In-house analytical capabilities supporting material and product characterization
- Microbiological laboratory capabilities (bioburden determination, endotoxin testing, LAL, for product and process control and sterility testing)

7 MANUFACTURING AND ASSEMBLY

- Injection molding under controlled environments
- Assembly of components, devices, and systems
- Bag manufacturing and complex fluid handling solutions
- Compliance with cleanliness requirement (cleanroom production ISO Class 7)
- Scalable production from pilot to serial manufacturing

8 SERVICES AND SUPPLY

- Management of sterilization, gamma, ebeam, EtO
- Compliance support, regulatory and technical documentation
- Quality management and full traceability
- Integrated logistics and reliable delivery

LAL: limulus amebocyte lysate , IQ: installation qualification, OQ: operational qualification, PQ: performance qualification.

Throughout the project, we work in close alignment with our partners' technical and business objectives to meet the demanding requirements of the medical, diagnostic, and healthcare sectors.

We guide each project from initial concept to sustained commercial manufacturing, ensuring every medical component is engineered, validated and produced for stable, long-term performance

A CDMO dedicated **to high-quality medical plastic components**

Healthcare companies often face increasing pressure to develop components that are more precise, more reliable and compatible with demanding regulatory and performance requirements.

Grifols Medical Components CDMO is designed to help bridge that gap by providing solutions that ensure consistency, manufacturability and long-term supply stability.

We bring structure, predictability and rigor to every step, ensuring components are ready.

Consumables components

(MTUs, twist-off, connectors, adapters, holders, plastic parts for in vitro diagnostics, pipette tips, racks...)

Medical device instruments

(surgical devices, medical device aggregations...)

Empty bags

in different types of materials and formats

Tailor made products

we can always adapt the product to customer requirements

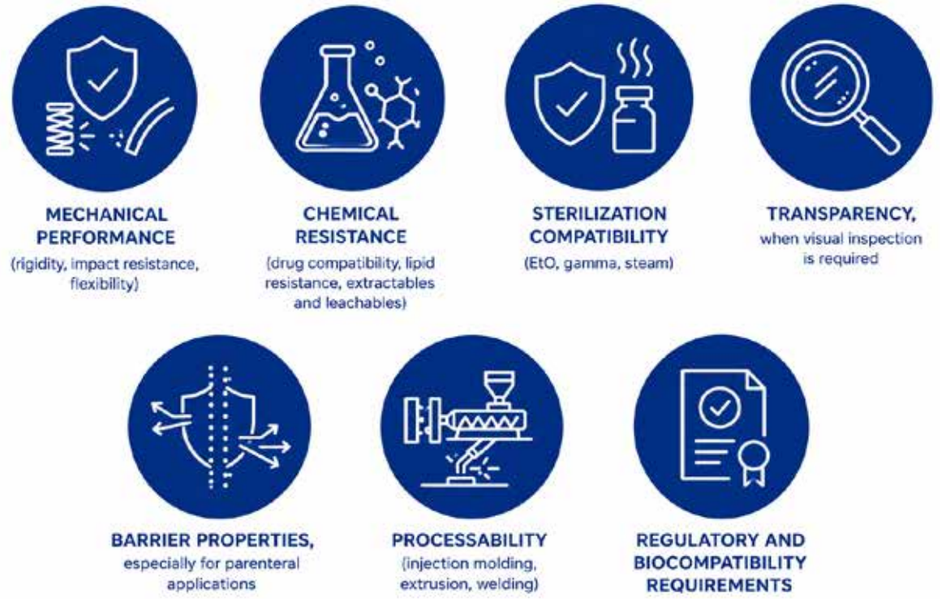
CDMO: contract development and manufacturing organizatio; MTUs: multi tube units

How to select the **right medical polymer**

Selecting the appropriate polymer is a complex process requiring a thorough understanding of both the specific medical application and the properties of the available material options and it is critical to ensure performance, processability, regulatory compliance, and cost-efficiency in medical device and component manufacturing.

At Grifols, we support our customers in choosing the most suitable material based on application requirements, sterilization method, mechanical properties, and fluid compatibility.

When selecting a polymer for medical components, we consider several criteria:



With advanced capabilities and a forward-looking operational mindset, we help our partners stay ahead in a rapidly changing medical plastics landscape and pharmaceutical standards.

Our **Medical-Grade Polymer** Portfolio:

Grifols works with a carefully selected range of medical-grade polymers to address diverse application needs. Each material offers a unique combination of mechanical, chemical, and processing characteristics, enabling us to adapt to different functional, regulatory, and performance requirements.

The following overview provides a comparative perspective to help guide material selection based on typical properties, advantages, and application areas.

MATERIAL	KEY PROPERTIES	ADVANTAGES	LIMITATIONS	TYPICAL APPLICATIONS
Acrylonitrile Butadiene Styrene (ABS)	• Tough, impact-resistant	• Easy to process • Cost-effective • Good surface finish • Suitable for EtO and Gamma irradiation	• Limited chemical resistance	• External housings, non-critical components
Polycarbonate (PC)	• Rigid, transparent	• High transparency • High impact resistance • Excellent dimensional stability • Suitable for EtO and Gamma irradiation	• Limited resistance to some chemicals	• Transparent components, diagnostic devices
Acrylonitrile	• Flexible, soft to semi-rigid	• Excellent chemical resistance • High flexibility • Good biocompatibility • Suitable for EtO and Gamma irradiation	• Lower stiffness compared to other polymers	• Tubing, liners, fluid pathways
Polyethylene (PE)	• High stiffness, low friction	• High mechanical strength • Excellent dimensional stability • Precision performance	• Not ideal for repeated sterilization	• Valves, moving parts, mechanical components
Polyoxymethylene (POM)	• Semi-rigid, lightweight	• Excellent chemical resistance • Good balance stiffness/flexibility • Compatible with EtO	• Moderate temperature resistance • Limited compatibility with gamma sterilization	• Tubing, connectors, containers, disposable systems
Polyvinyl Chloride (PVC)	• Flexible or rigid	• Good chemical resistance • Versatile (flexible/rigid grades) • Widely used in medical	• Environmental concerns (plasticizers) • Moderate temperature resistance	• Tubing, blood bags, fluid management

The materials behind each component have to be chosen with rigour and precision. An unsuitable medical polymer can mean device failure, regulatory rejection, or patient harm.

Laboratorios Grifols leverages advanced material expertise in the use of flexible films for parenteral solution bags, meeting the highest pharmaceutical standards including:

- Tri layer polyolefin films combining flexibility, strength, and chemical inertness.
- High barrier structures incorporating PET SiOx technology to reduce gas permeability and enhance product stability.
- High purity polyethylene based films with low extractables and leachables, ensuring excellent compatibility with sensitive formulations

At Grifols, we go beyond:

Selection
of technically suitable materials aligned with your application requirements

Colaboration
with qualified suppliers to ensure compliant manufacturing of medical devices and injection-moulded components

Tailored
material selection guidance based on your specific needs to optimize performance and cost efficiency

Validation-ready
solutions aligned with regulatory standards

Multi-polymer expertise
across device components and fluid management

This integrated approach ensures a seamless transition from concept to industrial production, reducing development risks while ensuring full compliance with medical and pharmaceutical standards.

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Tailor-made solutions, designed for you

When standard solutions don't fit, we design the right one for you. Grifols offer custom-made solutions specialized in the development and production of medical components and devices, transforming complex ideas into high-performance, regulatory-compliant products aligned with your specific needs.

Our R&D team works in close partnership with your experts, combining engineering expertise, manufacturing technologies, and deep industry knowledge to deliver innovative and scalable solutions. We support the full development journey to ensure precision, reliability, and efficiency. Continuous innovation and technical excellence are at the core of our market-leading position in custom device development.

We help
healthcare companies turn unique challenges into manufacturable solutions, meeting the highest standards of quality and safety.

Can't find what you're looking for? Let's create it together!

Our commitment to quality and compliance with regulations

European GMP
Good manufacturing practice for medicinal products in compliance with European regulations.

FDA cGMP (21 CFR Parts 210 & 211)
Good manufacturing practice for medicinal products intended for the US market.

ISO 13485
All products are developed, manufactured, and marketed under an ISO 13485-certified quality management system.

CE Certification
Compliance with European Medical Device Regulation (EU) 2017/745 (MDR) for selected medical devices.

MDSAP
Laboratorios Grifols holds Medical Device Single Audit Program certification, enabling multi-market regulatory acceptance.

FDA Establishment Registration
Registered manufacturing facility for products supplied to the US market.

FDA Quality System Regulation (21 CFR Parts 820 & 821)
Compliance with US medical device quality and traceability requirements.

21 CFR Part 4
Compliance with FDA regulations for combination products.

What sets us apart **from other CDMOs?**

At Grifols Medical Components CDMO, our differentiation comes from more than our manufacturing capabilities. We combine the strength of a global healthcare company with a highly specialized focus on medical components, enabling customers to rely as partner bringing stability, depth and long-term commitment to every collaboration.

Global industrial expertise

With decades of experience, our team ensures faster development and industrialization through validated processes, technical expertise and seamless global coordination.

A broad and evolving plastics portfolio

We manage an extensive portfolio of medical-grade plastic components, combining polymer engineering and validated manufactuting workflows to support our partners across multiple applications.

Solutions tailored to customers needs

Customized medical components and assemblies. Every design responds to specific needs. We adapt materials, designs, and molding parameters to meet customers specific requirements, ensuring optimal performance and seamless integration.

Certified excellence and robust compliance mindset

Built on a quality framework aligned with global healthcare standards, our operations are supported by recognized certifications and strong regulatory oversight. As a trusted partner, we are fully prepared for audits and the most stringent compliance requirements.

A Global Healthcare Company

Global Employer

Grifols, with more than 23.000 employees in over 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership in the industry.

Global Manufacturer

Grifols has the infrastructure to meet the needs of patients and customers worldwide including manufacturing facilities located in the US, Spain, Germany, Ireland, Switzerland and Australia.

Innovative

We conduct our own R&D programs and make strategic investments in promising start-ups and novel technologies. We also modernize our manufacturing facilities and develop novel processes to help ensure product safety and efficacy.

Grifols is a global healthcare company that since its founding in Barcelona in 1909 has enhanced the health and well-being of people around the world.

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Grifols International, S.A.
Parc empresarial Can Sant Joan, Av. de la Generalitat, 152-158
08174 Sant Cugat del Vallès, Barcelona - SPAIN
Tel. +34 935 710 500
hospital.division@grifols.com
www.grifols.com

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