

*Your trusted partner in*

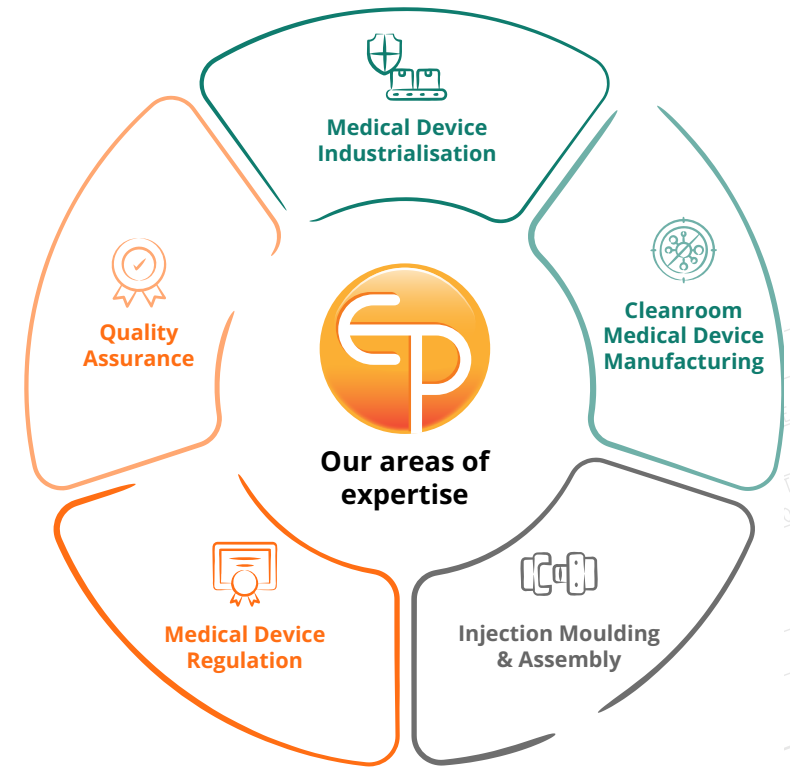
# **Medical Device Manufacturing**

*The leading UK partner  
for the manufacture and  
commercialisation of life  
science and medical devices.*

# Europlaz: Manufacturing excellence for Healthcare Innovation

Europlaz is a UK-based medical device and life science contract manufacturer operating under ISO 13485 and the FDA's quality system regulation. We specialise in complex, single-use or limited-use devices, typically produced in low to medium volumes (from thousands up to a few million units per year).

Our expertise in injection moulding, assembly, packaging and sterilisation, ensure a seamless manufacturing experience tailored to your specific requirements.



All electric moulding machines across 7 cleanrooms

**Precision manufacturing.  
Trusted quality.  
Dedicated partnerships.  
Welcome to Europlaz.**

# Who are Europlaz?

Europlaz has over 40 years' experience manufacturing medical components and devices.



We manufacture devices for diverse medical sectors including diagnostic, drug delivery, biotech, and pharmaceutical sectors.



ISO 13485 and FDA-registered manufacturing facility.



State-of-the-art cleanrooms, certified to ISO Class 7, for the manufacture of Class I, Class IIa, IIb and Class III medical devices.



Our clients range from start-ups to large international corporations. Europlaz is known for its flexibility and resourcefulness in handling projects of varying scales and complexities, an accomplished small to large batch manufacturer.



We are committed to quality, compliance and reliability, which is why we are a key long-term supplier for our customers.



Your contract

# Medical Device Partner

**Europlaz specialises in the end-to-end manufacturing of medical devices, ensuring a seamless transition from your concept to a market-ready product.**

## **Development Support**

- Small batch manufacture for development
- Prototype tooling and manufacturing processes
- 3D printing
- Performance testing
- Design for Manufacturing (DFM) and Design for Assembly (DFA)
- Capacity planning
- Process optimisation

## **Project Management**

- Small project management using DSDM approach to agile and stage gates
- Dedicated project manager and named engineering resources

## **Industrialisation**

- Tool design, mouldflow analysis
- Assembly equipment design
- Process validation
- Sterilisation validation
- Product performance testing and release procedures
- Packaging specification and testing
- Biocompatibility assessment and management
- Risk management
- Supply chain establishment
- Technical file authorship and holding





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Our expertise positions us as  
a trusted partner in ensuring  
compliance and market readiness.

# Cleanroom Manufacturing

Europlaz provides specialist cleanroom manufacturing services for Class I, Class IIa, IIb, and Class III medical devices. Our cleanrooms are purpose-built and certified to ISO 14644 standards, ensuring controlled levels of airborne particulate and microbial contamination.

- **Modern Cleanroom Facilities:** Precision injection moulding and complex medical component manufacturing in ISO-certified environments.
- **Flexible Assembly Options:** Manual, semi-automated, and fully automated assembly to suit both intricate and high-volume production.
- **24-Hour Manufacturing Capability:** Round-the-clock operations for flexible scheduling and time-critical projects.
- **Variable Batch Sizes:** From small pilot batches to high-volume production, with consistent quality and control.
- **Experienced and Reliable Team:** Skilled staff with over 10 years' average tenure, ensuring expertise and attention to detail.



# Injection Moulding

Europlaz is highly experienced in developing tooling for injection moulded components for medical devices, building a reputation within the medical sector for quality and complexity.

- Bespoke tooling designs optimised for capacity, efficiency, and the specific demands of medical device manufacturing such as lubricant free, live monitoring and modular designs to reduce NRE / CapEx costs.
- Capable of handling both low-volume and high-volume production runs, catering to diverse client needs.
- Access to a wide selection of technical polymer resins allows for tailored solutions to meet diverse application requirements.
- Automated systems enable rapid manufacturing cycles, producing large volumes of parts per hour with minimal waste, enhancing both speed and cost-effectiveness.
- Experience in:

Technique	Key Feature	Typical Use
Single Shot	High volume manufacture of simple or complex components made from a single material	Casings, functional components
Insert Moulding	Embeds preformed inserts into plastic parts	Metal-plastic hybrid components
Overmoulding (2k)	Adds a layer of material over a substrate	Multi-material parts for ergonomics or sealing

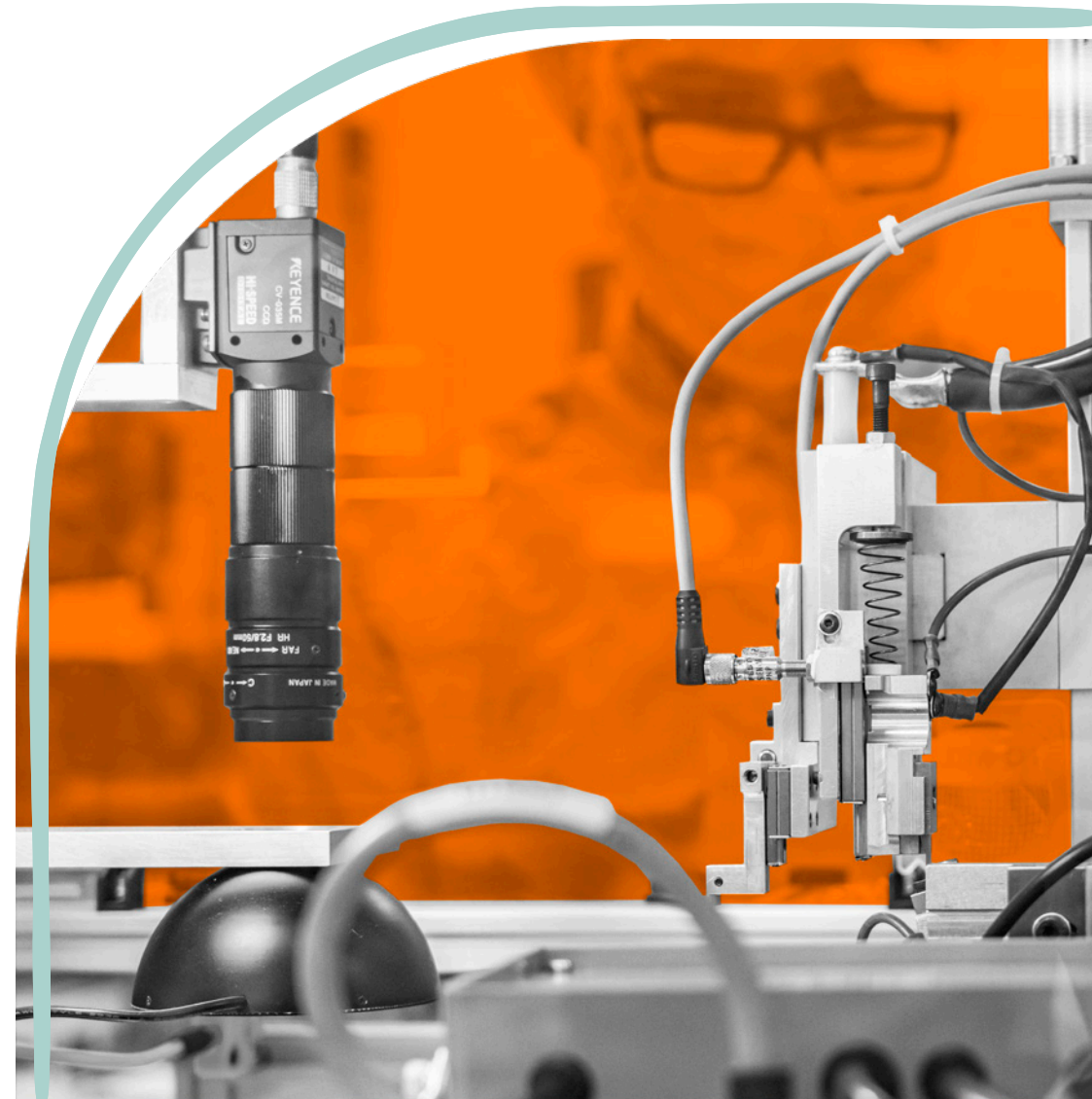
Each of these techniques play a crucial role in addressing the unique challenges of medical device manufacturing, ensuring safety and precision.

# Assembly Capabilities

At Europlaz, we specialise in delivering high-quality, precise medical device assembly, offering advanced solutions tailored to your product's unique requirements. Our experienced team ensures every component is assembled with the utmost accuracy and reliability, adhering to the highest industry standards.

We customise our assembly processes to perfectly fit your needs, providing a seamless approach to bring your medical device to life.

- **Advanced Bonding Techniques:** From ultrasonic and hot plate welding to adhesive and UV bonding, we use the latest methods for secure, durable assemblies.
- **Scalable & Cost-Effective:** Our adaptable production lines optimise efficiency, ensuring cost-effective solutions for low-to-medium volume demands.
- **Precision & Consistency:** Supported by cutting-edge equipment and a highly skilled team, we deliver accuracy, quality, and regulatory compliance in every project.
- **Customised Approach:** We tailor our assembly processes to your specific device requirements, including sterilisation, regulatory compliance, and sustainability needs.
- **Metrology:** Incorporating both contact and non-contact (vision-based) CMMs.



# Packing Solutions

We provide high-quality packing solutions to ensure your device is protected, sterile, and ready for distribution. Our specialised packing processes maintain product integrity while meeting stringent industry regulations. With a focus on precision and compliance, we offer a range of packing methods tailored to your specific needs, ensuring your products are safely sealed and ready for market.



- **Sterile Barrier Systems (SBS):** Tyvek® pouches, medical-grade paper pouches, and form-fill-seal blister packaging ensure product sterility.
- **Rigid Packaging:** Thermoformed trays, injection-molded containers, and clamshell packs provide durable protection.
- **Flexible & Barrier Packaging:** Foil laminates, polyethylene and polypropylene films, and aluminium foil pouches for moisture-sensitive products.
- **Protective Packaging:** Custom foam inserts, die-cut trays, and molded protective solutions safeguard delicate devices.
- **Pouch Packaging:** Peelable heat-seal pouches and header bags designed for secure and sterile storage.
- **Labelling & Sustainability:** UDI labels, tamper-evident seals, and eco-friendly packaging solutions, including recyclable and biodegradable materials.
- **Branding:** Custom branded packaging.
- **Cartoning:** For distribution and presentation packs.

# Additional services to facilitate manufacture

At every stage of your manufacturing journey, our additional services are designed to enhance efficiency, compliance, and product reliability. From streamlined order fulfilment and advanced sterilisation solutions to comprehensive supply chain management and rigorous product testing, we provide the critical support needed to bring your innovations to market with confidence.

- Order fulfilment.
- Supply chain management.
- Process validation.
- Sterilisation.
- Product testing.
- Packaging testing.
- Biocompatibility.
- Risk management.
- Logistics.
- Technical file authorship and holding.



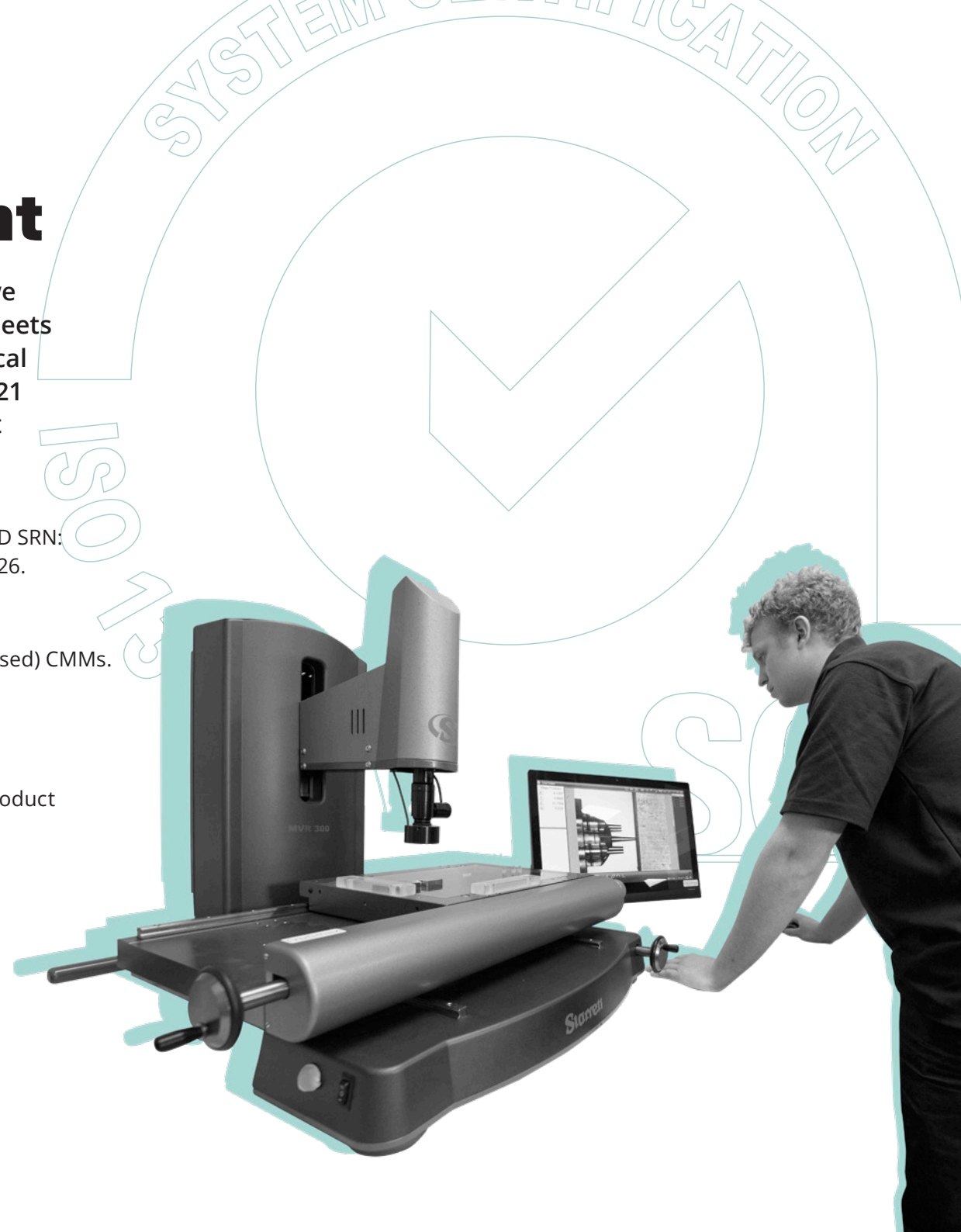
The background is a teal-colored technical drawing of a mechanical assembly. It features various lines, circles, and dimension lines. A large, semi-transparent number '6' is overlaid on the left side. Several dimensions are visible, including '86.00 CTR' on the left, '45.00' at the bottom, and a vertical stack of dimensions '65.09', '75.09', and '99.09' on the right. A dimension 'Ø 1.00' is also visible on the far right.

Our strength lies in solving complex manufacturing challenges, helping customers deliver safe, effective medical devices to market with confidence.

# Regulatory & Quality Management

Our dedication to quality is at the heart of everything we do. With a certified Quality Management System that meets ISO 13485 standards, complies with the European Medical Device Regulation (MDR 2017/745), and aligns with FDA 21 CFR Part 820, we deliver products that meet the highest regulatory requirements.

- Our notified body is SGS, MHRA account number: 6090, EUDAMED SRN: GB-MF-000031950 and our FDA registration number is 3004180226.
- Advanced product quality planning (APQP).
- Metrology incorporating both contact and non-contact (vision-based) CMMs.
- UKCA/CE marking and legal manufacturer.
- Technical file generation.
- Europlaz holds legal manufacturer status for several customer product ranges and proprietary products: Class I and Class IIa.





From early engagement to full production, we work as an extension of our customers' teams - proactive, committed, and always focused on results.

# Customer acknowledgements

Here is what a small selection of our customers have to say, ranging from small start-ups to global blue-chip medical device suppliers.

*"The team are very professional, knowledgeable, flexible, collaborative and trustworthy. Europlaz's contribution has played a significant role in getting us to where we are now."*

**Cyted**

*"We're pleased to be working with industry leaders such as Europlaz to help us scale – not just in the UK, but globally."*

**PocDoc**

*"Very responsive customer service team who are flexible to the needs of a large, complex organisation."*

**GSK**

*"Europlaz has an excellent reputation for supplying high quality products. They are market-leading in design and innovation and strongly emphasise sustainability and the environment."*

**Fannin**

*"Europlaz are a high valued, key supplier to Performance Health who provide an excellent service. Their knowledge of manufacturing medical devices is critical to the success of any new product."*

**Performance Health**

abbvie

 Cyted

 eventum  
orthopaedics

 FRESENIUS  
KABI



**GSK**

ingenion<sup>®</sup>  
MEDICAL

 Inspiration  
HEALTHCARE

Johnson & Johnson

**MAQUET**  
GETINGE GROUP

Medtronic

**NHS**

 PERFORMANCE  
HEALTH<sup>®</sup>

**SARTORIUS**



 UCL

Experienced  
Leadership

## Team

Our leadership team brings a wealth of experience, and a shared commitment to driving innovation and excellence in every aspect of our business. With diverse expertise and a unified vision, they guide Europlaz toward delivering exceptional value to our customers.



*"I'm passionate about helping customers bring innovative medical technologies to life. At Europlaz, we don't just manufacture — we partner, problem-solve, and adapt to our clients' needs."*

**Rory O'Keefe**  
**Commercial Director**

Dream dinner party guest: Barack Obama



*"I'm excited about the future of life sciences in the UK, where innovation, quality, and collaboration are driving real progress. At Europlaz, we're proud to support visionary companies."*

**Katy O'Keefe**  
**Director**

Dream dinner party guest: Georgia O'Keefe



*"It's rewarding to lead such a committed production team. I focus on driving efficiency, quality, and consistency so our customers can rely on us every time."*

**John Grima**  
**Operations Director**

Dream dinner party guest: Henry Ford



*"I'm particularly excited by the work we're doing in the bioscience space. Our team brings technical rigour and process focus to meet the demands of advanced medical device manufacturing."*

**Ian Goodacre**  
**Technical Director**

Dream dinner party guest: Jarvis Cocker



*"I'm driven by excellence and compliance. At Europlaz, quality isn't just a department — it's part of our culture, giving customers complete confidence in what we deliver."*

**Richard Buckmaster**  
**Head of Quality**

Dream dinner party guest: Hannah Fry



*"Regulations shouldn't be a barrier to innovation. At Europlaz, we see them as the foundation for trust and quality, helping customers deliver safe, reliable medical devices."*

**Alastair Fry**  
**Head of Regulatory Affairs**

Dream dinner party guest: Tim Peake

# Europlaz:

## Your Trusted Partner in Medical Device Manufacturing

### Expertise:

- With over 40 years of experience, Europlaz delivers complete medical device manufacturing services to the diagnostics, drug delivery, biotech, and pharmaceutical sectors.

### Capabilities:

- We provide end-to-end manufacturing solutions – from medical device industrialisation through to market-ready products – supported by advanced injection moulding, assembly, packaging, and sterilisation.

### Facilities:

- Our ISO Class 7 cleanrooms support the manufacture of Class I, IIa, IIb, and III medical devices. We operate 17 all-electric moulding machines across 7 cleanrooms, enabling efficient, high-quality production.

### Certifications:

- We are certified to ISO 13485:2016, FDA-registered, and fully compliant with CE/UKCA marking and the European Medical Device Regulation.

### Advanced Manufacturing:

- Our technical capabilities include overmoulding, insert moulding, and automated assembly and packaging systems – enabling precision, repeatability, and scalability.

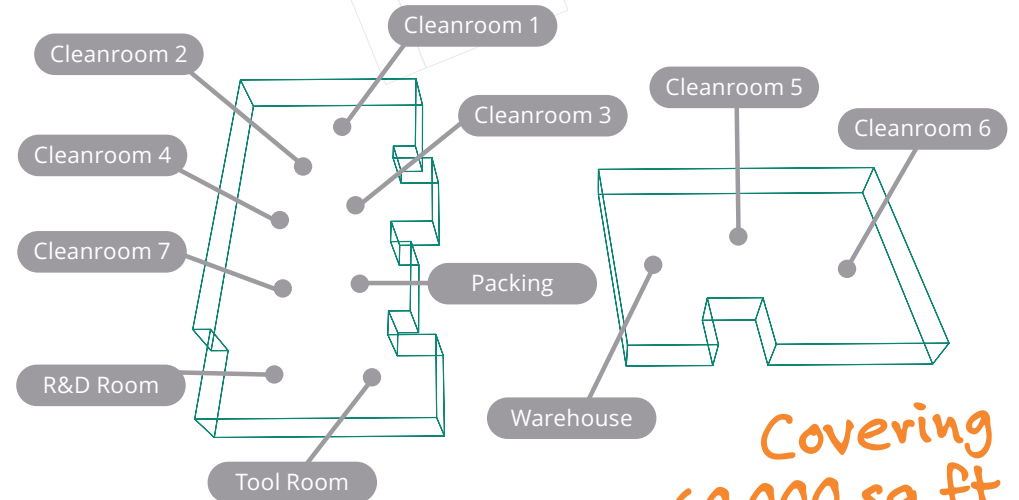
### Customer-Focused:

- We partner with start-ups and multinational companies alike, offering tailored, flexible solutions with a proven track record of success for major healthcare providers.

### Global Reach:

- Europlaz supports its clients with robust supply chain and distribution management, underpinned by rigorous regulatory compliance and quality assurance.

Let Europlaz turn your medical innovation into reality.



Covering  
60,000 sq ft



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