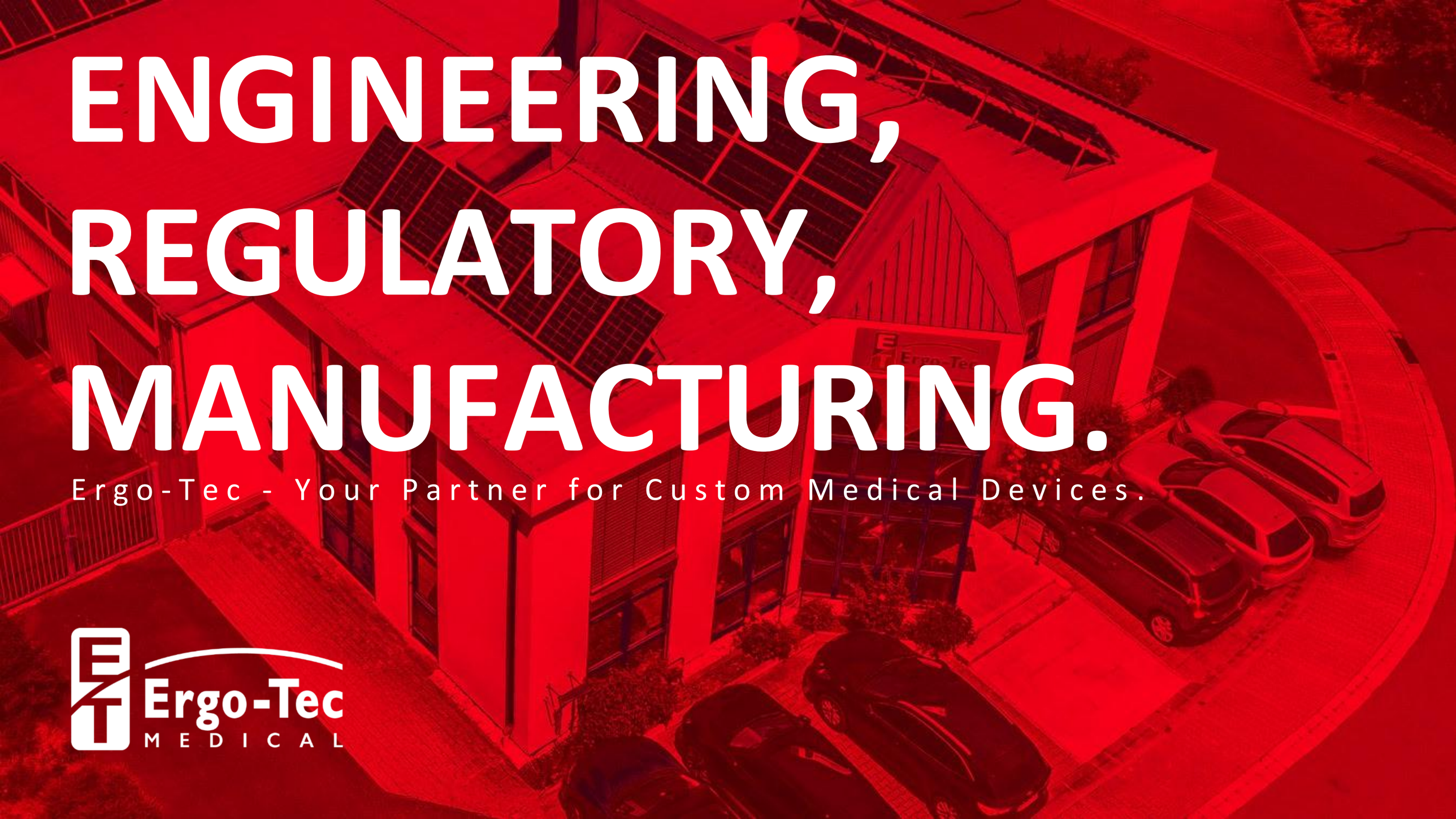

ENGINEERING,
REGULATORY,
MANUFACTURING.
Ergo-Tec - Your Partner for Custom Medical Devices.
Ergo-Tec
MEDICAL

BUILT ON EXPERIENCE

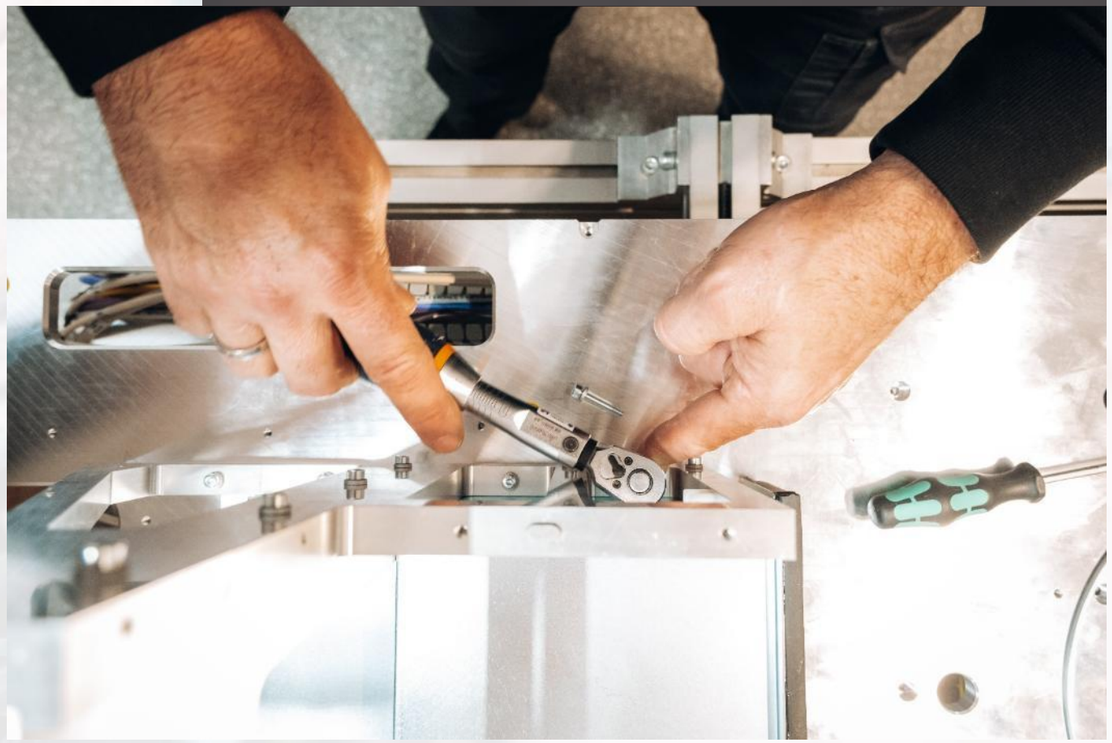
Ergo-Tec supports companies in turning medical device ideas into market-ready products – from concept to production, with development, regulatory preparation, and manufacturing closely aligned.

Founded in 2000 as a family-owned company in Bavaria, Ergo-Tec works with both industry and research partners across a wide range of medical applications.

Why companies choose Ergo-Tec:

- One partner instead of multiple interfaces across development, regulatory, and production
- Reduced coordination effort through clearly structured teams and direct communication
- Short decision paths in an owner-led organization
- Experience in projects where technical development and regulatory requirements must be aligned early
- Over 25 years of hands-on experience in medical device development

QUALITY MADE IN GERMANY
Designed to reduce risk and keep projects on track.

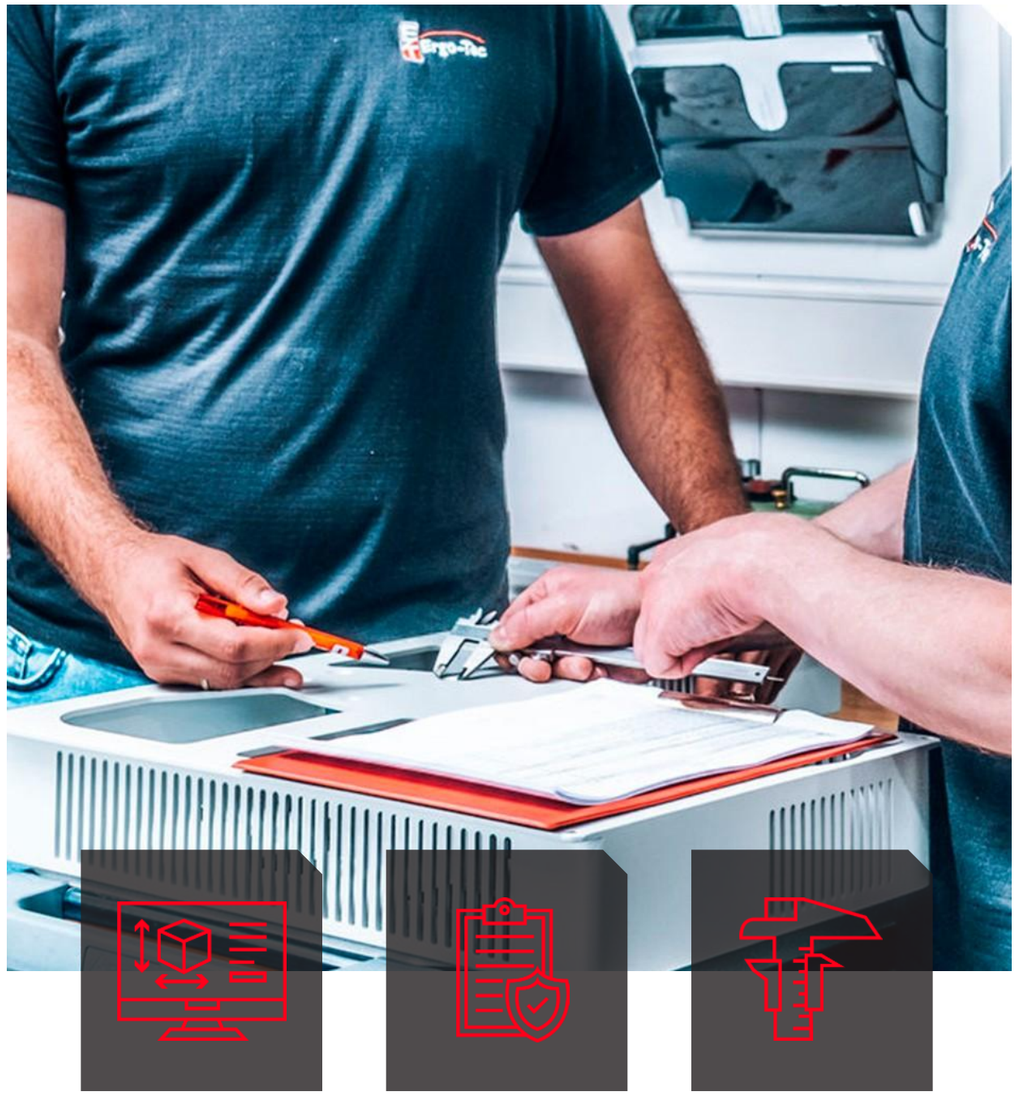


INTEGRATED MEDICAL DEVICE SERVICES

Between the first product concept and series production lie many decisions and coordination steps.

When engineering, regulatory preparation, and manufacturing work together from the start, processes become clearer, risks are reduced, and the path to market remains predictable.

Whether a project is still in concept phase, already developed, or preparing for production, Ergo-Tec brings these areas together – taking over development, prototyping, approval processes, and manufacturing across the full process or in specific phases.



A RELIABLE PARTNER FOR MEDICAL TECHNOLOGY

For more than 25 years, Ergo-Tec has been working in medical device development and manufacturing – across a wide range of projects and collaboration models.

Much of this experience comes from devices for patient positioning – from examination and treatment chairs to operating tables and hospital beds.

These applications typically involve electrically adjustable systems and place high demands on safety, usability, and integration into clinical workflows.

ENGINEERING

Ergo-Tec MEDICAL

REGULATORY

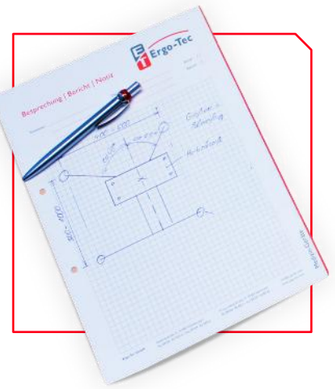
MANUFACTURING

FROM IDEAS TO PRODUCTS

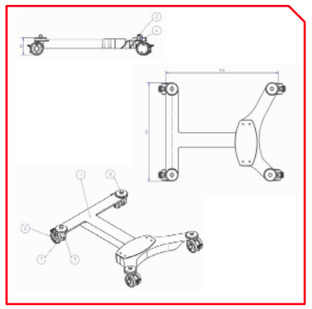
Technically thought through. Practically planned.

Early visualization and prototyping support sound decisions and help avoid later design changes.

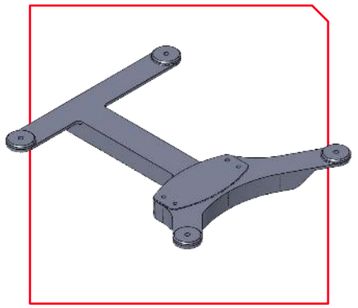
Concept sketch



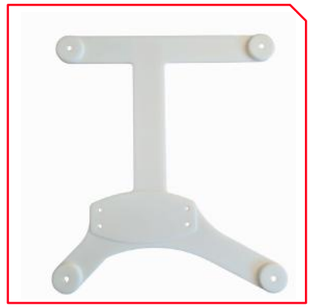
CAD drawing



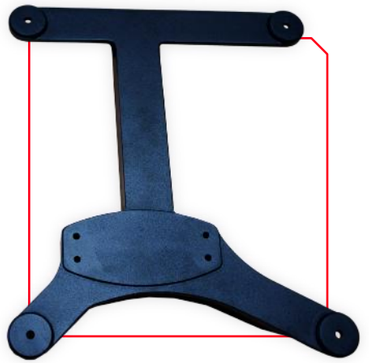
CAD model



3D-printed model



Prototype



Final product

ENGINEERING

INTELLIGENTLY DEVELOPED

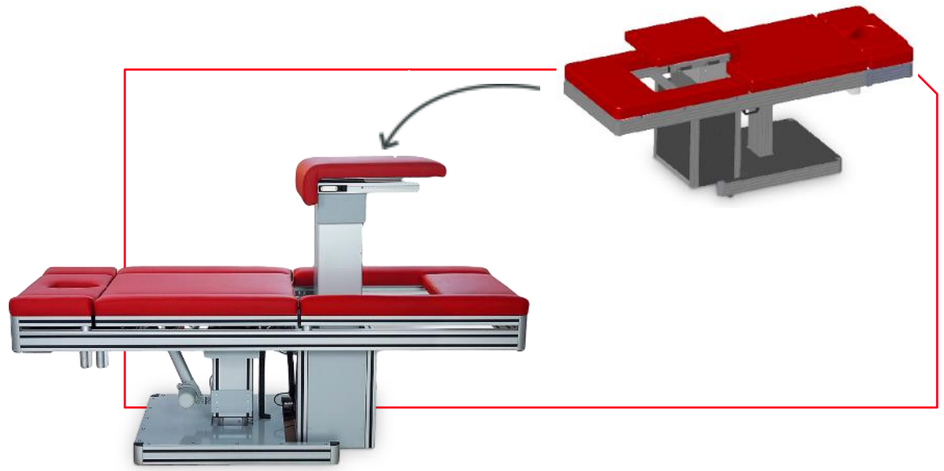
Thoughtfully designed. Planned for market readiness.

- **Concept & Planning:**
  A product idea is translated into a clear development plan, including defined requirements.
- **Design & Engineering:**
  Models and simulations make functions tangible early on and support confident decisions.
- **Prototypes & Testing:**
  Prototypes quickly show what works – and where refinement is needed.
- **Optimization:**
  Ergonomics, functionality, and economic feasibility remain in focus throughout development.

A clear development structure ensures that technology, functionality, and feasibility align from the outset.

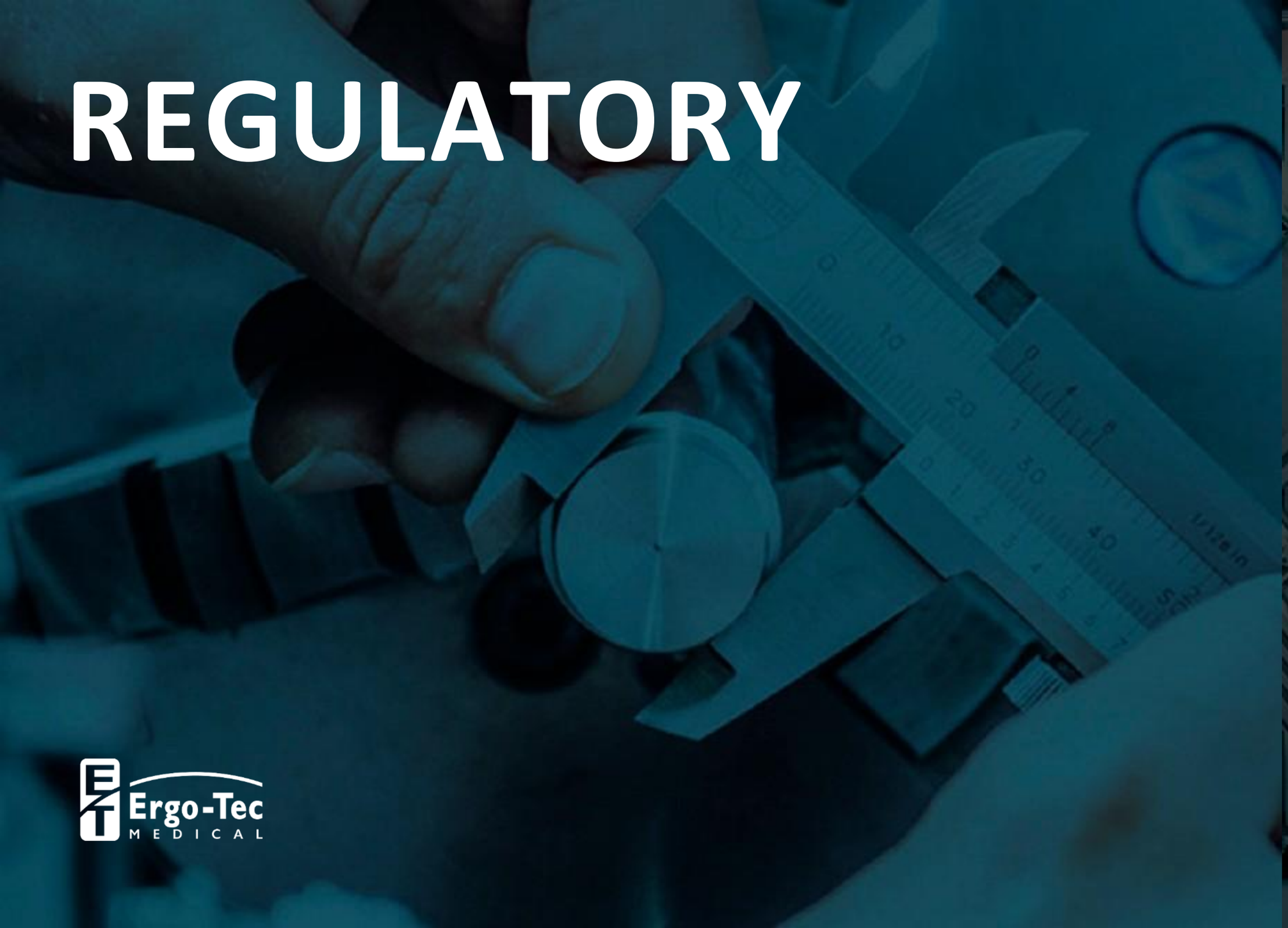
- **Step-by-Step Refinement:**
  Through ongoing feedback and coordination, the product is continuously sharpened.

From CAD model to ready-to-use product:



ENGINEERING

REGULATORY



Ergo-Tec MEDICAL

MANUFACTURING

ENGINEERING

COMPLIANCE MADE STRAIGHTFORWARD

For a clear, streamlined approval process.

Certificate registration no.: Z-25-014-S-E

CERTIFICATE

Berlin Cert GmbH

DAkkS

hereby certifies that

Ergo-Tec GmbH
Gewerbestrasse 2, 91489 Wilhelmsdorf, Germany

and further locations
Industriestrasse 6, Wilhelmsdorf, Germany
storage of patient positioning systems

has implemented and uses a quality management system for the following scope of application

Development, production, sales and distribution of patient positioning systems

The audit report no. B-25-014-S-RZ provided confirmation that the requirements in the standard

DIN EN ISO 13485:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
Medical devices - Quality management systems
Requirements for regulatory purposes

have been fulfilled.

Issued: 25.03.2025
Valid from: 01.04.2025
Valid until: 31.03.2028

Dipl.-Ing. Martin Tettke
Signature of authorised representative

BERLINCERT Dovestraße 6 • 10587 Berlin • Germany
+49 30 58582160 • info@berlincert.de • www.berlincert.de
afnor GROUP

Regulatory approval determines whether products can enter the market as planned and whether go-to-market activities are properly prepared.

Clear workflows and complete, traceable documentation help avoid delays and follow-up requests - keeping projects on schedule.

- Risk analysis
- Documentation
- In-house testing (e.g., tilt test, load test)
- Product certification
- ISO 13485–certified processes

REGULATORY

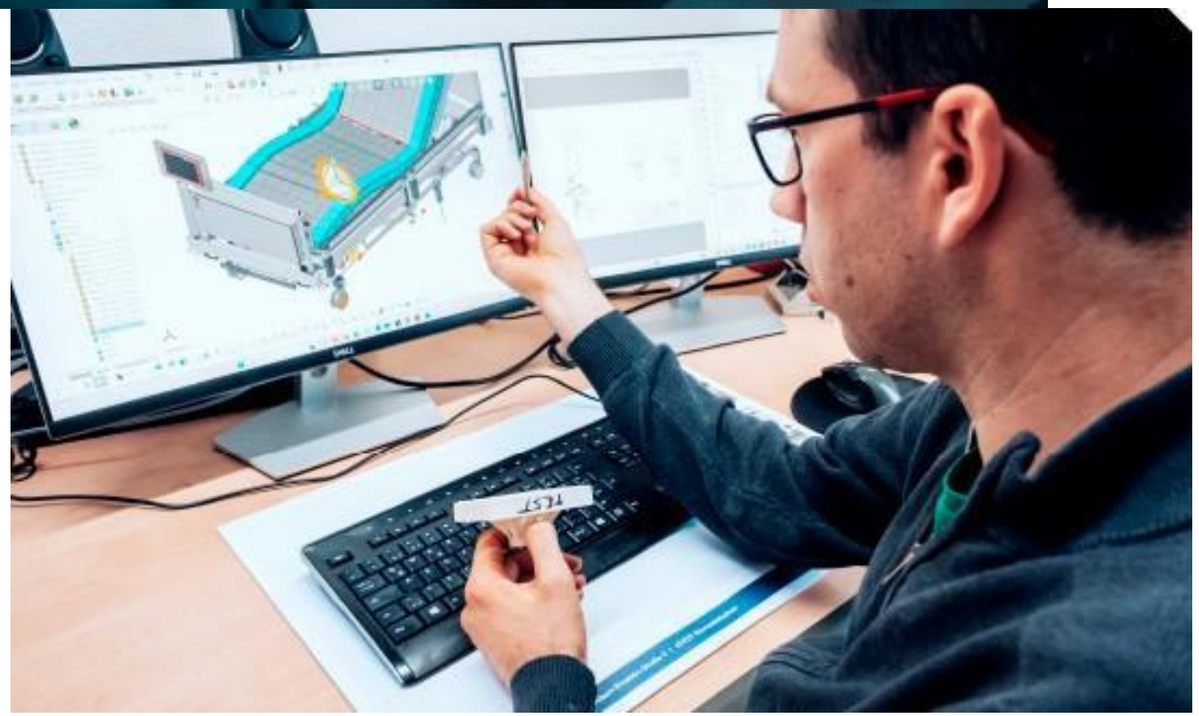
A DIRECT PATH TO APPROVAL

This ensures products can enter the market as planned.

- **Release processes** protect not only the product, but also timelines, budgets, and planned market launches.
- **Complete documentation** covers all relevant steps – from risk analysis to certification.
- **In-house testing** evaluates function, durability, and safety early and in a traceable manner – for the protection of users and patients.
- **Every component** remains clearly traceable, from the first part to the finished product.

ALIGNED WITH APPLICABLE STANDARDS:

Your product is developed in line with relevant requirements and supported throughout the approval process from start to finish.



REGULATORY

MANUFACTURING

ENGINEERING

REGULATORY

Ergo-Tec MEDICAL

WHEN MANUFACTURING RUNS SMOOTHLY

Everything under one roof - without added complexity.

From procurement through assembly and testing to worldwide shipping, one step follows the next.

Planning and coordination keep processes transparent and schedules on track – freeing up internal resources on the customer side.

- Supplier sourcing
- Material procurement
- Quality inspection
- Series production
- Domestic and international shipping

PROVEN SUPPLY CHAINS:

Reliable planning and on-time delivery, backed by a network of long-standing, audited partners.

MANUFACTURING

RELIABLE IN EVERY PROJECT

Manufacturing exactly where it is needed

Ergo-Tec supports start-ups, manufacturers facing capacity limits, or companies looking to outsource - flexibly and cost-effectively.

Some projects require individual components or subassemblies. Others require full series production.

Ergo-Tec supports both - from assemblies to complete devices, in small to mid-volume series.

An ERP-driven production system keeps material availability, schedules, and quality in view. When required, supplier sourcing is integrated as well – for projects facing capacity constraints, overloaded internal manufacturing, or the need for a dependable series partner.

- Subassemblies
- Final device assembly
- Wiring

MANUFACTURING

ONE SYSTEM – ONE FLOW

Data, processes, and components are seamlessly connected and remain clearly traceable.

WHY ERGO-TEC?

Keeping projects predictable.

Fewer handoffs, clearer project visibility.

Manufacturing at the right scale

Predictable projects instead of surprises

Time and resources used efficiently

ENGINEERING, REGULATORY, MANUFACTURING – AT THE RIGHT SCALE:

Ensuring a clear path to series production.

LET'S TALK ABOUT YOUR PROJECT.

Ergo-Tec GmbH

Alexander Dürsch
Gewerbestraße 2
91489 Wilhelmsdorf
Germany

Phone: +49 9104 82969-0
www.ergo-tec.com
a.duersch@ergo-tec.com

Save our contact details: