



MEDICAL DEVICE MANUFACTURERS:

How GERGONNE's vertical integration secures and accelerates your projects

In the highly demanding healthcare sector, choosing an industrial partner is not simply a matter of cost or production capacity. For medical device (MD) manufacturers, risk management, regulatory compliance, and speed to market are critical priorities and obligations.

At GERGONNE, we have made the strategic choice to pursue vertical integration. From the formulation of medical adhesives to the final cutting in a cleanroom, we manage every step of the value chain.

Discover how this unique organizational structure translates into concrete, competitive advantages that safeguard your medical projects, from the initial idea to final packaging.

1. Design and Co-Development: designing the product together

The success of a new medical device is determined as early as the design phase. This is where GERGONNE's vertical integration truly comes into its own: we support your R&D teams well before the first cut is made.

- **Co-development and rapid prototyping:** Our engineers work in synergy with your teams. Our dual expertise in chemistry and mechanics allows us to drastically accelerate trial-and-error cycles and the refinement of industrial prototypes. GERGONNE is a true design partner: you provide the idea and the need, and our teams develop the product with you, from adhesive formulation to the device's final architecture.
- **A genuine advisory role:** Depending on the maturity of your project, our teams guide you in selecting materials (adhesives, films, carriers, liners) as well as design choices (device architecture, ergonomics, cutting) to achieve your performance goals while keeping costs and development timelines under control.
- **Component customization:** We incorporate your customization needs right from the design phase: printing on the liner to guide the user in applying and using the device, branding with your logo and brand identity, or printing on the packaging for an optimal product experience.

2. Bespoke formulation and coating: the core of our expertise

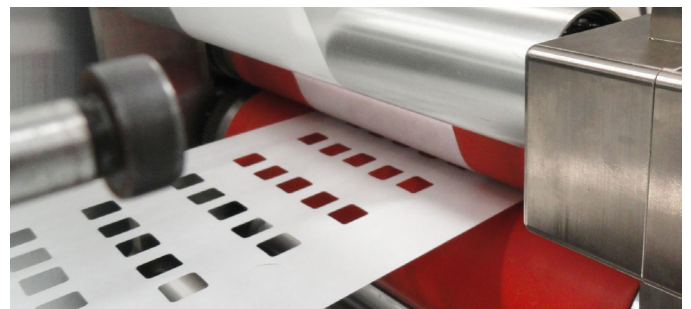
Unlike a traditional converter or slitter, GERGONNE specializes in the formulation and coating of adhesives. In our Adhecare line, we offer polyurethane films and skin adhesive solutions (adhesive tapes based on acrylic adhesives and silicone gel) that are perfectly suited for sensitive skin or long-term applications.

- **Guaranteed biocompatibility:** our formulations are rigorously tested and validated in accordance with ISO 10993 (cytotoxicity, irritation, sensitization).
- **Technical flexibility:** we can adjust the adhesive weight, the choice of carrier (breathable polyurethane film, nonwoven fabric), and the type of liner to precisely meet the performance requirements specified in your technical specifications.

3. From jumbo rolls to finished products: high-precision manufacturing

Unlike a raw material supplier, our integrated approach goes beyond simply supplying rolls. We have a state-of-the-art machine park to bring your components or finished medical devices to life.

- **Complete manufacturing in a cleanroom:** Our coating and cutting capabilities, both performed in a cleanroom, ensure compliance with microbiological and particulate requirements throughout the entire manufacturing process.
- **Advanced cutting technologies:** Thanks to our high-precision rotary cutting machines, we can handle even the most complex operations (synchronized multi-tool cutting, perforation, printing, and multi-layer lamination, etc.).
- **Primary and secondary packaging:** We perform primary product packaging directly on the production line, closest to the production process. Our hot-sealing and cold-sealing solutions allow us to package each device in an individual



pouch within a controlled environment. In addition to this primary pouch, we can also handle secondary packaging (cases, outer packaging, and cartoning) to deliver a finished product ready for storage and distribution according to your logistics requirements.

- **Sterilization management:** Depending on your organization's needs, GERGONNE can handle the sterilization process or leave this step to you if you prefer. In either case, GERGONNE will advise you on the compatibility of materials with the chosen sterilization method (ethylene oxide or radiation) as well as the proper management of the sterile barrier.

4. Complete control over quality and traceability (ISO 13485)

In the field of wound care or surgical devices, even the slightest material defect is unacceptable. By integrating all manufacturing processes, GERGONNE eliminates the complex chain of liability associated with multiple subcontractors.

- **A single quality approach:** our entire production chain is governed by the ISO 13485 standard for medical devices.
- **End-to-end traceability:** from the chemical raw material to the ready-to-use die-cut part, each batch is tracked within a single, unified management system.

- **Drastically reduced risk of contamination:** our operations (coating, lamination, cutting, packaging, etc.) are performed in cleanrooms within our own facilities, minimizing intermediate transport and external handling.

5. Comprehensive regulatory support: from assistance to CE marking

The regulatory framework for medical devices is strict and constantly evolving. With the entry into force of the **European MDR Regulation 2017/745**, rigorous documentation and a thorough understanding of the technical documentation have become essential requirements for placing a product on the market. GERGONNE is certified by BSI and tailors its support to the role you wish us to play.

- **GERGONNE as a subcontractor:** the client remains responsible for the product's CE marking. GERGONNE acts as a subcontractor and provides all the technical data necessary for the client to compile their technical dossier and regulatory documentation. The medical device may be Class I, Is, IIa, IIb, or III.
- **GERGONNE as a manufacturer:** GERGONNE handles the CE marking and provides a "turnkey" product to its client. The medical device may then be Class I or Is.



LONG-TERM PRODUCT RELIABILITY AND STABILITY

By controlling our entire supply chain, we spare you the burdensome change validation procedures imposed by third-party suppliers—which are often costly, time-consuming, and complex to manage. This stability directly contributes to lowering the total cost of the device over its entire lifecycle.

Conclusion: a trusted partnership for your medical innovations

By entrusting your medical device project to a partner with a proven track record in vertical integration, such as GERGONNE, you're doing much more than just securing your production. You gain agility, reduce your time-to-market, and optimize your overall costs thanks to an integrated production chain, without the markups of successive intermediaries.

This organizational structure also limits the impact of international logistics disruptions, ensuring supply continuity and the flexibility to adapt to your procurement forecasts, all under the control of a quality management system.

Our end-to-end expertise is designed with a single goal in mind: to turn your regulatory and technical requirements into a guaranteed business success.

GERGONNE, your single point of contact: one supplier, one audit, one quality agreement, and a dedicated contact to manage your entire project, from design to delivery.

Do you have a project for a new medical device or are you looking for a custom skin adhesive?

Contact our sales and R&D teams today so we can review your specifications and work together to design your solution for the future.

CONTACT-US - Contact us – For further information, please visit www.gergonne.com or contact us directly on +33 4 74 73 39 01 or by email at the following address: contact.fr@gergonne.com.