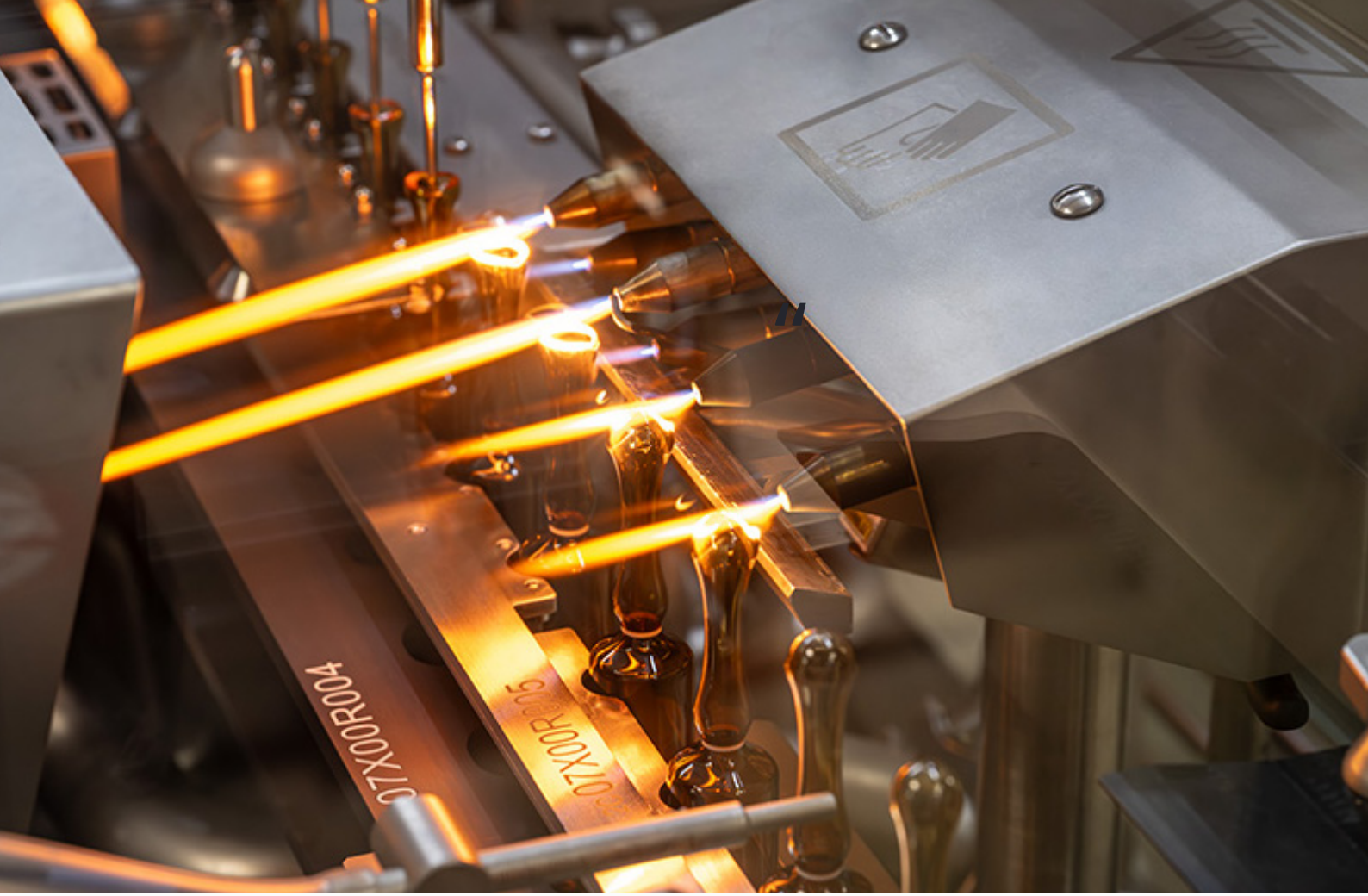


Customer Case Study

Early MDR certification built on clear communication

How Teknimed combined structured planning and clear communication to support continuity and growth.

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Background and drivers

Teknimed is a global medical device manufacturer specializing in orthopaedic solutions, including bone cement, bone substitutes and polymers. Founded over 35 years ago and led by CEO Carole Léonard since 2011, the company has grown significantly – from €6.5 million turnover and 35 employees to €21 million and 100 employees, with 80% of its business conducted internationally. Teknimed also manufactures products under private-label agreements for several leading global orthopaedic companies, remaining the legal manufacturer while supporting their products across international markets.

As regulatory requirements evolved, Teknimed set a clear ambition: to be among the first manufacturers to successfully transition its full portfolio to the EU Medical Device Regulation (MDR). This required not only technical excellence but a strong regulatory strategy and a trusted organization to support global compliance.

For manufacturers navigating regulatory change or evaluating their Notified Body, achieving continuity, clarity and confidence is critical.

Teknimed at a glance

35+ YEARS EXPERIENCE	€21m TURNOVER
100 EMPLOYEES	80% INTERNATIONAL BUSINESS

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Challenges

The MDR transition presented complex and far-reaching challenges:

- Increased regulatory scrutiny and significantly higher documentation requirements.
- Complex product classifications, including implants and products involving animal tissue and medicinal substances.
- Substantial demand on internal resources across R&D, clinical, regulatory and quality teams.
- High compliance costs and extended development timelines.
- The need to maintain business continuity while prioritizing MDR activities, avoiding disruption to operations, timelines, and market supply for both Teknimed and its private-label customers.



Carole Léonard
President & CEO, Teknimed

"Together, we turned regulatory complexity into an opportunity for improvement and growth.



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Solution

Teknimed adopted a proactive, strategic approach – selecting BSI as its Notified Body early in the MDR journey and signing its agreement in September 2019, shortly after BSI's designation.

Key elements of the approach included:

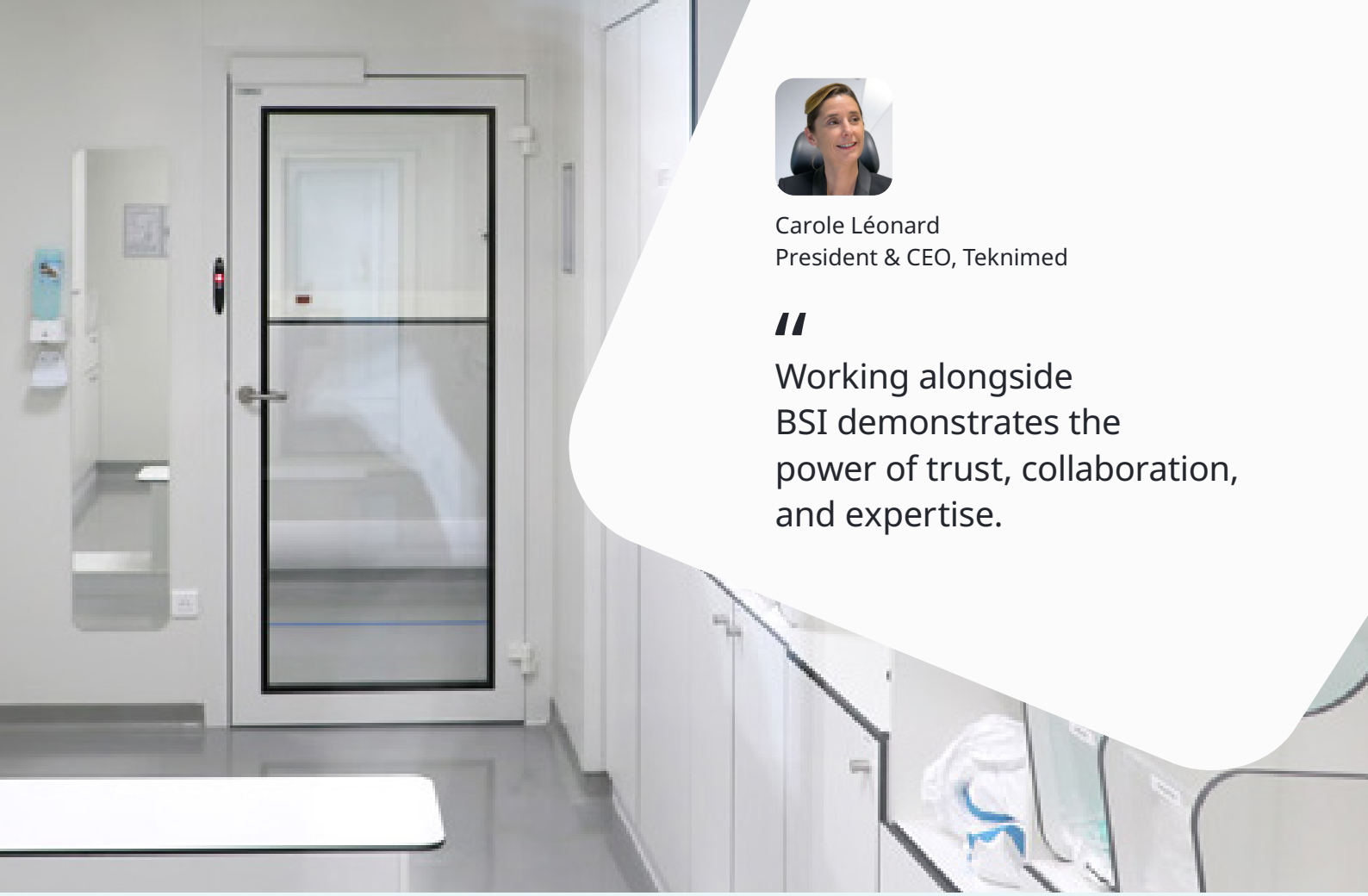
- **Early adoption strategy:** Committing to MDR ahead of many competitors.
- **Worst-case product selection:** Prioritizing the most complex products to accelerate learning and reduce downstream risk.
- **Cross-functional taskforce:** Integrating clinical, R&D, regulatory and quality expertise.
- **Project governance:** Implementing a PMO structure to maintain timelines and coordination.
- **Continuous collaboration:** Engaging closely with BSI's Scheme Manager and reviewers through interactive iterative review cycles.
- **Learning loops:** Embedding insights from each review into future submissions.

1. Early adoption strategy
2. Worst-case product selection
3. Cross-functional taskforce
4. Project governance
5. Continuous collaboration
6. Learning loops

This structured certification process ensured that regulatory requirements were not only met, but fully understood and embedded into Teknimed's processes.



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Carole Léonard
President & CEO, Teknimed

> "Working alongside BSI demonstrates the power of trust, collaboration, and expertise.

Results

Through its structured and forward-thinking approach, Teknimed achieved:

- Known as an early MDR-compliant organization.
- This early and successful MDR transition for its Class III devices and then across its extended portfolio.
- Strengthened compliance aligned to pharmaceutical-level standards.
- Seamless facility transfer and operational expansion without disruption.
- Facilitated regulatory approvals in global markets (e.g.,Korea in under one year).
- Increased confidence from major partners including leading global manufacturers.

This enabled Teknimed to manage complex regulatory changes without disruption, ensuring continuity for customers and partners. Teknimed was also able to secure new business opportunities, as partners sought reliable, compliant suppliers in an evolving regulatory landscape.

Benefits of working with BSI

Teknimed highlights several key benefits of choosing BSI as its Notified Body:

- Deep regulatory expertise and global recognition.
- Clear, constructive and responsive communication.
- A collaborative approach.
- Early guidance materials on the MDR compliance journey to set client expectations and requirements, including MDSAP.
- Continuity of engagement throughout the certification lifecycle.

This enabled Teknimed to navigate complexity with confidence and maintain momentum throughout a demanding transition.

For manufacturers considering a change in Notified Body, this level of clarity, continuity and collaboration is essential to supporting a low-risk, predictable transition.

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A conformity journey built on trust

At the core of the project was a strong, transparent relationship between Teknimed and BSI. Regular dialogue, collaborative working and mutual trust helped both teams address challenges proactively and efficiently.

By working collaboratively with BSI, Teknimed was able to identify issues at early stages, reduce delays and continuously improve its processes.

Looking ahead

Building on its MDR success, Teknimed is continuing to expand globally, with a strong focus on entering new markets such as Japan and maintaining best-in-class regulatory standards.

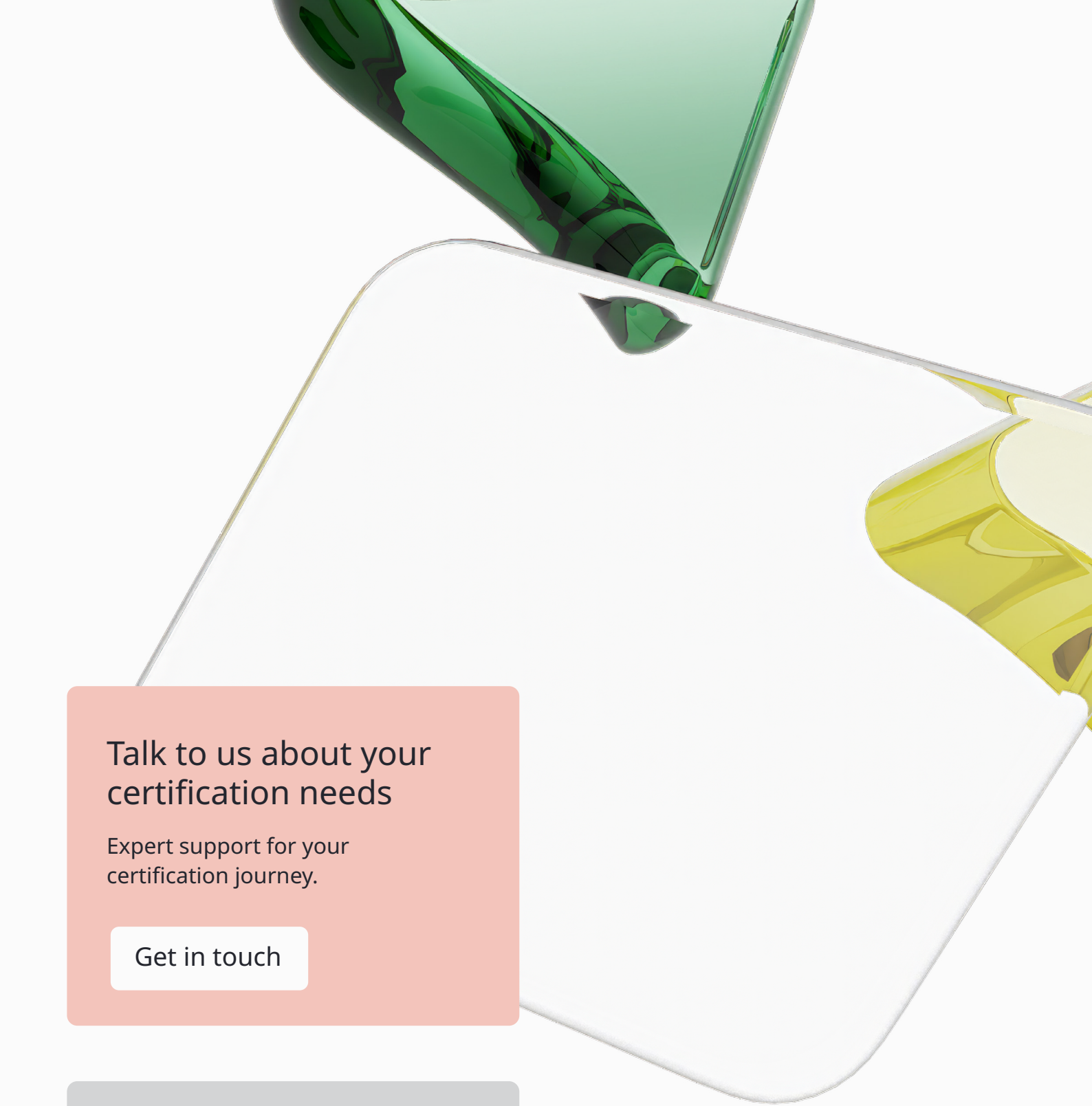
With BSI as a long-term certification provider, the company is well positioned to navigate future regulatory developments while continuing to innovate and deliver safe, high-quality products worldwide.



Carole Léonard
President & CEO, Teknimed

"We created a true confidence-based relationship, with open communication at every stage.

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Talk to us about your certification needs

Expert support for your certification journey.

Get in touch

Explore certification transfers with BSI

Move your certification with greater clarity and confidence.

Explore transfers

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