MedTech IN FRANCE

Europe, the future world leader in medical technologies

MEDTECH IN FRANCE – INNOVATION FOR OUR PATIENTS

MedTech in France is the **voice of the French medical technology industry,** a trusted partner of the French authorities. We bring together more than 50 French MedTech companies, from e-health to surgical robotics, masks, respirators, plasters to dental filling material, heart valves, or x-ray machines. Our members produce in France.
Our ambition is to facilitate patient access to the **most innovative medical technologies**, to bring economic and organisational benefits to the health system, and to foster **excellence** within the sector.

The **COVID-19 pandemic** has confirmed the need for a robust regulatory framework for the healthcare sector.

The medical technology industry is working to **support all ongoing efforts** to counter the pandemic, through tests, protective equipment, and ensuring a safe environment for healthcare professional.

What is a MedTech?

All technology that cares for patients, such as:

- **ultrasounds to treat benign breast tumours**
- **artificial heart**
- **advanced wound healing dressing...**

France is a strong MedTech innovation hub, comprising 1,500 companies and worth more than €30 billion, with an annual growth of 4%[1]

SMEs – A MOTOR FOR MEDTECH INNOVATION IN EUROPE

SMEs are a motor for innovation to discover and produce new medical devices (MDs). This has significant **social and economic implications.**

1. SMEs make up **80%** of the European MedTech industry and employ **nearly 760,000 people** across Europe[2]
2. In **France, 93%** of MedTech companies are SMEs[3] and startups, providing **90,000 jobs** and is continuously growing[1], while France is 11th on the list of the most innovative countries[4] globally
3. In **Germany**, the MedTech industry employs **over 215,000 people**; each MedTech job guarantees **0.75 jobs** in other industries[5]

THE REGULATORY CONTEXT – THE MDR

The new Medical Devices Regulation (MDR) will ensure a high level of safety and health protection for patients. It will greatly increase the **requirements** for manufacturers. The requirements will include expanded clinical evidence and intensified supervision by designated notified bodies (NBs) to assess the conformity of MDs before they can obtain the CE mark. **MedTech in France** shares the high level of ambition of the MDR. Our members produce innovative medical equipment. Made in France, our products comply with **EU standards of quality and safety.**

The challenge of getting products to market in time

The MDR introduces **new classification rules.** As some MDs have a new class, they require additional assessment by NBs. Those NBs also need time to achieve certification. As a result, there is a **serious shortage of NBs capacity,** making it difficult for manufacturers to conduct the legally required conformity assessment procedures and transfer all existing medical device certificates into the MDR **in time**.

According to the latest survey conducted by the European Association for Medical Devices of Notified Bodies, **17,937 CE-certificates** of MDs will **expire** in **2024**[6] and **only 25 certified NBs to examine the files**[7].

70%

70% of French MedTech companies face product discontinuation because of challenges related to the new MDR[8]

90%

Companies have increased resources (recruitment, R&D investments, and regulatory budgets) by 20-90% in order to comply with MDR[10]

60%

So far, 60% of French[9] and German[8] MedTech companies haven't received any MDR certificate

100%

For 100% of German companies, the costs of a conformity assessment procedure increased across all MDs[8]

Tackling increased burden for SMEs

Stricter MDR requirements are here to protect patients, but they require a considerable amount of **additional work,** which SMEs often **cannot afford** due to a lack of sufficient manpower and resources. Some companies are considering **relocating their production** to cheaper countries outside the EU (e.g., China) and **product portfolio adjustments**, meaning that tried and tested medical products that are urgently needed may no longer be available on the market.

In France, **92%** of French citizens found it important that MDs are manufactured within the EU[10]

The regulatory context: The Pharmaceutical Strategy for Europe and MedTech

The Pharmaceutical Strategy for Europe aims to promote innovative technologies and address market failures. While the medical technology and pharmaceutical regulatory frameworks are clearly and rightly distinct in terms of involved actors and approval procedures, there are some points where both sectors should be considered in conjunction in terms of regulatory approval. This is the case for:

- **Companion diagnostics:** Medical devices meant for the safe and effective use of medicinal products
- **Device-drug combinations:** Medical devices incorporating ancillary medicinal substances
- **Co-packaging:** Medical devices co-packaged with medicines
- **Certain tissue-engineered products:** Regulated as advanced therapy medicinal products (ATMPs)

MEDTECH IN FRANCE: A TRUSTED AND CONSTRUCTIVE PARTNER OF THE EU

MedTech in France encourages policies that help the medical technology industry meet **Europe's growing healthcare needs and expectations.** We remain **committed** to working with EU institutions and Member States as trusted partners, discussing ongoing challenges and opportunities, and improving the access of citizens and national health systems to **medical technology innovation.**

(1) Picard and al., 'Réflexions stratégiques sur la politique industrielle en matière de dispositifs médicaux', 2019. (2) Eurostat, 'Employment and Population Statistics. 6 WHO, 2019, Global Health Expenditure Database', 2021. (3) 'Snitem, 'Panorama 2019 et analyse qualitative de la filière industrielle des dispositifs médicaux en France', 2020. (4) Global Innovation Index 2021, World Intellectual Property Organization – WIPO (HERE). (5) BVMed Report no 03/18, 2019 (HERE). (6) Survey, European Association for Medical Devices of Notified Bodies survey, November 2021. (7) NANDO MDR database, 13 December (HERE). (8) Survey, MedTech in France, September 2021. (9) Survey, Ifop for MedTech in France 'The perception of the French MedTech industry by French citizens', November 2021 published by the Journal du Dimanche. (10) Survey, Bundesverband Medizintechnologie (BVMed), September 2021.

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