Saint Denis, April 23, 2024

Medical devices market under pressure: AFNOR Certification authorized to issue CE marking

France is the second largest medical device market in Europe and yet a large number of players are unable to obtain the European pass: the CE marking. In question ? The lack of Notified Bodies (NB) and the increase in regulatory requirements. By becoming the 2eFrench Notified Body authorized to issue CE marking for this type of product, AFNOR Certification intends to reduce the queue and facilitate market access for a greater number of manufacturers.

- To market a medical device in the EU, it is necessary to obtain the CE marking, proof of its compliance with Regulation (EU) 2017/745. Medical devices are divided into several classes depending on the amount of risk they involve.
- AFNOR Certification was jointly designated by the ANSM (National Agency for the Safety of Medicines and Health Products) and the European Commission to assess the conformity of medical devices with this regulation and issue the CE marking to compliant manufacturers.
- The lack of French NOs and the regulatory complexity have led a number of French medical device manufacturers, some with high added value, to abandon the European market. This situation has led the Ministry of the Economy and Finance and the Ministry of Solidarity and Health to publish a call for applications, in order to benefit from an increased offer of regulatory certification in French.
- These obstacles to CE marking are a major obstacle to the innovation of medical devices and a risk for public health policies serving patients and caregivers.

- The arrival of AFNOR Certification, as 2eON French, will make it possible to process a greater number of requests, and thus make products available to patients more quickly.
- To achieve this, AFNOR Certification is actively recruiting and training new auditors and examiners specializing in certain product families.

Revitalizing the French medical device industry

The entry into force on May 26, 2021 of the new European regulation has disrupted the conditions of access to the medical device market, since the cursor has been set to a very high level of requirements. The complexity of the rules and the increased burden for CE marking, understandable in view of the health risks and the growing expectations of patients in terms of quality and safety, have resulted in increased requirements for notified bodies, the number of which has been divided by three in Europe, and by higher costs and delays for manufacturers.*"Our country, which is nevertheless the second largest medical device market in Europe, had up to*

*today only one notified body, compared to 10 in Italy and Germany",*explains Thomas Lommatzsch, director of AFNOR Certification's medical offering.

"*For AFNOR Certification, this new French Notified Body status is of major importance with strategic and economic impacts. Our role is now to facilitate the recognition and influence of French medical devices in France and abroad and to maintain a high level of quality and innovation.*»underlines Julien Nizri, general director of AFNOR Certification.

No reindustrialization of MD without CE marking

The sector is made up of 93% VSE/SMEs and generates 32.5 billion euros in turnover, including 10.6 from exports and generates 84,000 direct jobs, almost 100,000 if we include outsourcing. (Source: SNITEM). The economic and social weight of medical devices has made their integration into the vast France 2030 plan essential.
To support the wave of reindustrialization of medical devices in France and contribute to fully integrating medical devices into public health policies for the benefit of patients and caregivers, AFNOR Certification will train auditors and product examiners that the market lacks.

Secondly, AFNOR Certification intends to bring out on the one hand devices embedding artificial intelligence, which will have to comply with the provisions of the IA Act, and on the other hand digital devices in e-health, market in boom in which French start-ups are particularly innovative and well placed.

Zoom: what is CE marking?

To obtain CE marking for its medical device, a manufacturer must meet several requirements, including:

- Write technical documentation
- Have your product tested in the laboratory
- Establish and maintain a quality management system
- Submit a CE marking request to a Notified Body
- Write a declaration of conformity

About AFNOR Certification

AFNOR Certification is a leading independent third-party organization in France, thanks to its certification and evaluation services for systems, services, products and skills. A subsidiary of the AFNOR association, it has been a historical observer of quality and safety approaches for more than 10 years. AFNOR Certification offers a local service thanks to 37 representations on five continents and 12 regional delegations in France. It mobilizes 1,600 qualified auditors to meet the needs of its clients on more than 60,000 sites around the world. AFNOR Certification runs the NF certification system and offers several signs of confidence, certifications, labels and evaluations such as the AFAQ certification, the ESSMS evaluation in the medico-social field and the European Ecolabel.https://certification.afnor.org/

Press contact: Anne-Lise François – 06 34 53 78 16 (I respond to text messages)presse@afnor.org