Marketing authorisation of medical devices and in vitro diagnostic medical devices

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The marketing of medical devices (MDs) and in vitro diagnostic medical devices (IVDMDs) is governed by a European regulatory framework. This framework sets out the “essential requirements” in respect of health and safety that manufacturers must comply with to guarantee the safety and reliability of their devices. The CE mark affixed by the manufacture guarantees this conformity.

To be awarded a CE mark, the manufacturer must compile a technical dossier showing evidence proving the quality and safety of the device. Depending on the risk class of the device, an independent accredited body (or “notified body”) is involved in the CE marking process. This body assesses the conformity of the device and the manufacturer’s quality system and issues, if the assessment is satisfactory, a certificate of conformity allowing the manufacturer to affix the CE mark on its device. CE marking is valid for a limited period. The suitability of the technical dossier and the manufacturer’s organisation must be the subject of further periodic assessments by the notified bodies.

Once released to market, the device is the responsibility of the manufacturer that markets it. The manufacturer must monitor its performances and safety, check that no problems arise in use, in order to take preventive or corrective measures where applicable.

In Europe, the so-called “competent” health authorities are responsible for market surveillance and for designating notified bodies.

Key messages

In France, ANSM is responsible for market surveillance, and for designating and monitoring French notified bodies.