"LEGACY" MEDICAL DEVICES

With **EU Regulation 2023/607 (in force from 20 March 2023)** amending EU Regulation 2017/745 (in force from 26 May 2021), legislators have established **a transitional regime allowing EU economic operators to continue marketing existing (and place new) medical devices on the market that were CE marked under former regulations**. The foregoing devices are referred to "legacy" medical devices. The regulations also apply to Turkey, Iceland, Norway and Liechtenstein**.**

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The new transitional periods are as follows:

a) **until 31 December 2027 for class III and implantable class IIb** medical devices;
b) until 31 December 2028 for class IIb medical devices other than those mentioned in point a), for class IIa medical devices and for class I medical devices
c) provision has been made for the '**automatic' extension of the validity of certificates expiring after 19 March 2023;**
d) provision has been made for the "**conditional" extension of the validity of certificates that expired before 20 March 2023**; the time limit impeding the resale of medical devices already placed on the market after 26 May 2025 has been removed.

For the more 'hazardous' devices, i.e. those belonging to higher classes, there is a shorter transitional period, while for those with less risk, belonging to lower classes, have a longer period. In addition, it must be noted that medical devices of classes higher than I (IIa, IIb and III) must be certified by notified bodies, whose function is to assess their performance and safety.

However, **the number of notified bodies is inadequate for the number of new certification requests. This has resulted in a longer certification timeframe,** with the risk that some manufacturers may not be covered by the transitional period, despite having submitted a timely application for certification.

Manufacturers who have taken advantage of the transitional period would be advised to submit an application for certification renewal by 26 May 2024. If such an application has already been submitted, 26 September 2024 becomes the date by which the contract with the notified body must be signed.

The above-mentioned deadlines are mandatory, therefore violation of Article 27, paragraph 1, of Legislative Decree 137/2022 (which prohibits **the unlawful placing on the market of non-compliant medical devices) could give rise to a fine ranging from €24,200 to €145,000.**