



A New Financial Burden on Companies in the Medical Device Sector

On 9 February 2024, the Ministry of Health published the criteria and procedures for the collection and allocation of resources pertaining to the so-called '*Fund for the governance of medical devices*', (pursuant to Articles 28 of LD no. 137/2022 and 24 of LD no. 138/2022 implementing Regulations (EU) 2017/745 and 2017/746), as part of a National Programme dedicated to medical devices and aimed at assessing, monitoring and directing innovation in healthcare through a multidisciplinary process called HTA (Health Technology Assessment).

Specifically, the decree applies to manufacturers or distributors of medical devices, large equipment and in vitro diagnostic medical devices that are sold to the National Health Service.

Starting from the current year, this Fund will be financed by the annual payment by the aforementioned companies of a share equal to 0.75% of the value of their turnover with NHS bodies, calculated net of value added tax, achieved in the financial year preceding the year of payment.

As for the payment methods, the Interministerial Decree provides that the companies manufacturing or distributing medical devices:

- from 1 November to 31 December of each year, pay the annual quota due to the State budget revenue chapter No. 3616, established for this very purpose; and
- by 31 December of each year, transmit to the Ministry of Health a declaration, pursuant to Presidential Decree No. 445/2000, containing the data relative to turnover and the contribution quota determined, with simultaneous certification of the payment made.

As of this year, therefore, companies in the medical device sector will be subject to a new form of 'taxation' to the detriment of their business activity and which is in addition to the issue of payback, which is currently pending before the Constitutional Court.



Image by Racol Studio on Freepik