Priority question for written answer P-001914/2022
to the Commission
Rule 138
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Subject: Implementation of the regulation on in vitro diagnostic medical devices: lack of notified bodies

On 26 May 2022, Regulation (EU) 2017/746 on in vitro diagnostic medical devices will enter into force. It lays down new provisions for a wide range of products, including pregnancy tests, X-ray devices and genetic tests. Under this regulation, medical devices that have until now been certified by the manufacturer themselves will be subject to stricter requirements and thorough assessment by a notified body.

Transitional measures will apply to some devices but not all of them. However, with the implementation of the new legislation upon us, the number of notified bodies is largely insufficient and companies in the sector are unable to place new medical devices on the market as these bodies are not available to even make a start on the certification process. Not only does this have financial consequences for companies that have invested in developing these new tools, but it also prevents European patients from being able to benefit from them.

1. What measures will the Commission take to address the difficulties faced by the sector?

2. Will the number of notified bodies to increase significantly over the coming months, especially in countries where none are currently available?