Question for written answer E-000409/2022
to the Commission
Rule 138
Marion Walsmann (PPE)

Subject: Implementing the Medical Devices Regulation

On 26 May 2021, the revised Medical Device Regulation (MDR), which provides for more robust requirements for the certification of medical devices, entered into force. This entails, in part, re-certification of already verified technical documentation which, due to the limited number of notified bodies, creates serious implementation difficulties, especially for small and medium-sized enterprises.

1. According to the Commission’s assessment, how many notified bodies are currently accredited for the certification of medical instruments across Europe, and how many product groups have been withdrawn from the previous certificates by the notified bodies? What action is the Commission taking to overcome the serious bottlenecks concerning notified bodies?

2. How can certification by notified bodies in other European countries be made faster, simpler and cheaper for European small and medium-sized enterprises?

3. What action does the Commission plan to take to address supply shortages due to the disappearance of end-of-life products or to prevent redundancies and investment freezes among European SMEs in the medical technology sector?