Question for written answer E-003427/2022
to the Commission
Rule 138
Gerolf Annemans (ID)

Subject: Problems with applying for certificates for medical devices

Medical devices must be certified. With Regulation (EU) 2017/745 of 5 April 2017 (Medical Devices Regulation), new certificates were required as part of the transition from the Medical Devices Directive to the Medical Devices Regulation. Due to the shortage of notified bodies, varying interpretations of the Medical Devices Regulation, and the lack of transparency, many companies have failed to obtain a new certificate, preventing them from selling their products and thus suffering financial damage.

1. Is the Commission aware of any companies facing difficulties as a result of the transition to the amended regulatory framework?

2. Is the Commission aware that there were said to have been problems with the external certification service DQS and, if so, were these rectified and what action, if any, was taken?

3. Was provision made, or is it being made, for a correct interpretation of transitional measures?