Question for written answer P-002465/2019
to the Commission
Rule 138
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Subject: Certification by notified bodies under the Medical Devices Regulation (MDR)(EU 2017/745) and the In Vitro Diagnostic Medical Devices Regulation (IVD) (EU 2017/746)

With the entry into force of the MDR (EU 2017/745) and the IVD (EU 2017/746) on 26 May 2020, stricter requirements shall apply for the certification of medical devices. It is important that these requirements come into effect on time. Many medical devices that were assigned to Class I in accordance with the legislation in force, will be assigned to a higher class and will require certification by a notified body.

According to a reply to a question to the German Federal Government, the Commission has so far approved 2 out of 41 applications from notified bodies. In the event of an unregulated exit by the United Kingdom from the EU, any notified bodies established there will lose their certification status and certificates issued there will also cease to be valid, so that a recertification process will be required, thus further increasing the need for notified bodies.

However, while there is an increased need for notified bodies, their number is very limited. As a result, there is a danger of bottlenecks in medical care in the EU. This is reflected in recent press reports. The German Hospital Association has expressed similar concerns. The German Government also assumes that, as things stand, such bottlenecks cannot be excluded.

Already last year, the European Parliament drew attention to this impending scenario and warned of such supply bottlenecks.

What measures has the Commission taken to date to guarantee the health care of European patients?