Question for written answer E-002352/2019
to the Commission
Rule 138
Andreas Glück (Renew)

Subject: Impact of the EU's Medical Devices Regulation

The EU Regulation on medical devices threatens to create bottlenecks in the supply of surgical instruments and other medical devices. Manufacturers have to submit new studies on products some of which have been tried and tested for decades, while the assessments required are demanding and their nature is, in part, unclear. New documentation requirements will also impose even more red tape on doctors than they already face. At the same time, the only assessors available are TÜV Süd and the British BSI, which is not nearly enough, and the impending Brexit could further exacerbate the situation.

What arrangements is the Commission making, based on what current knowledge, in order to prevent any shortages of supply as a result of the new Regulation?