

**Question for written answer E-002807/2025  
to the Commission**  
Rule 144  
**Jan-Peter Warnke (NI)**

Subject: Medical devices regulation (MDR)

The Commission received an obligation to submit a proposal to Parliament to revise the current MDR by the end of November 2025. It has been requested so urgently as the application of the current regulation is having devastating consequences for patients, doctors and medical device manufacturers in the EU, in particular SMEs.

1. When will a revision of the valid MDR be provided?
2. To what extent has the Commission been informed of the wide range of initiatives in Europe through associations, patient organisations, doctors' organisations and, for example, the hearing held in Parliament on 28 March 2025?
3. What influence does the excessive level of red tape currently in place in the EU have on the revision of the MDR?

Submitted: 9.7.2025