Question for written answer E-000690/2025
to the Commission
Rule 144
Niels Fuglsang (S&D)

Subject: Medical devices

Medical devices are governed by two EU regulations whose overall objective is to ensure patient safety: the Medical Devices Regulation and the In Vitro Diagnostic Medical Devices Regulation.

It appears, however, that the legislation is configured in a way that makes re-use difficult and creates unnecessary financial and administrative burdens.

Here is a real-life example: a municipal assistive products centre wants to repair a wheelchair by replacing a broken armrest. The new armrest is the same as the old one, but the product number is different. The repair can't be done because in this case the municipality would assume the role of 'manufacturer', along with the product liability for the wheelchair as a whole, including the motor, wheels and batteries. The upshot of this is that medical devices that are otherwise in order are not being reused.

With the above in mind:

1. Is the Commission aware of this problem?

2. Is this an area in which the Commission intends to change the rules to ensure patient safety and focus on the opportunities to promote a more circular economy?

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