

(English version)

**Question for written answer E-000690/25
to the Commission
Niels Fuglsang (S&D)
(13 February 2025)**

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?

Submitted: 13.2.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(2 May 2025)**

Regulation (EU) 2017/745 on medical devices ⁽¹⁾ (MDR) contains specific provisions on the roles and obligations of economic operators (Articles 10 to 16), as well as on the reprocessing of devices (Article 17).

Section 14.4 of Annex I to the MDR prescribes that devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively, while Section 23.4 of the same Annex lays down requirements regarding the information to be supplied when a device is reusable under certain conditions.

Aspects related to the repair of medical devices (MD) are not specifically regulated in the MDR; they are rather covered by national legislation of the Member States.

However, in cases as the one referred to by the Honourable Member, Article 16 of the MDR applies. It prescribes that the obligations on manufacturers are assumed by a distributor, importer or other natural or legal person when they change the intended purpose of a MD already placed on the market or put into service, or modify a MD already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

However, if the repair is carried out according to the relevant information and instructions on maintenance duly provided by the manufacturer, this should not adversely affect the performance and safety of the MD.

In such latter case, there would not be any need to have a different identification number of the MD, nor the natural or legal person who carried out such repair would have to assume the role and obligations of a 'manufacturer'.

The Commission would also like to inform the Honourable Member that the targeted review of the MDR is ongoing, and it will consider all issues related to the application of the current rules.

⁽¹⁾ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>).