

(English version)

**Question for written answer E-000744/25
to the Commission
Costas Mavrides (S&D)
(18 February 2025)**

Subject: The risks of microplastics produced by plastic orthodontic aligners

This inquiry concerns the escalating public health crisis stemming from the widespread use of plastic orthodontic aligners. Given the increasing prevalence of orthodontic treatment across Europe, there are valid concerns about the resulting human ingestion of microplastics. Users wear their plastic aligners for 22 hours a day, over 1 to 2 years (or more). The aligners are also renewed every week. These aligners then degrade into microplastics, which are subsequently directly ingested by patients.

Considering the potential harmful effects of the presence of microplastics in the body, and bearing in mind the relevant EU regulations such as the Medical Devices Regulation ⁽¹⁾, as well as the EU rules on the restriction of hazardous substances, can the Commission answer the following:

1. Is the Commission aware of this issue concerning plastic orthodontic aligners? And is it aware of the findings of medical studies on the impact of microplastics on the human body resulting from their indirect ingestion?
2. Are there any existing or proposed regulations concerning the safety of materials used in the manufacture of orthodontic aligners specifically addressing the potential for the release of microplastics and their direct ingestion?

Submitted: 18.2.2025

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

Regulation (EU) 2017/745 ⁽¹⁾, the ‘Medical Devices Regulation’ (MDR) sets the obligation for manufacturers of medical devices to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products, and processing residues, that may be released from the devices.

In addition, the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body must be reduced as far as possible and special attention must be given to nanomaterials.

Fulfilment of those requirements and the safety of CE (*Conformité Européenne*) marked medical devices placed on the market under the MDR is ensured by the conformity assessment procedure, which, for medium and high-risk products, involves also an independent notified body.

¹ Regulation (EU) 2017/745 of 5 April 2017 on medical devices, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.
(¹) <http://data.europa.eu/eli/reg/2017/745/2025-01-10>