Question for written answer E-000156/2022
to the Commission
Rule 138
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Subject: Regulatory gaps in the Medical Devices Regulation are leading to single market issues

Across the EU, a number of national political debates have been focusing on air purification technology. Policymakers have been discussing the effectiveness of air purification devices and whether or not they can mitigate the spread of COVID-19.

These devices – which must be differentiated from HEPA filtration devices – do not fall under the scope of the Medical Devices Regulation since individual patients do not come into direct contact with them. This is despite their obvious medical applications, which have seen many manufacturers claim their devices can eradicate harmful viruses like COVID-19, among others, from the air. As such, they are currently unregulated at EU level.

Growing awareness of these devices has led to varied opinions being formed on their effectiveness, which is leading to contradictory national legislation across the EU Member States.

1. Given the implications that these unilateral initiatives on air purification devices could have for the harmony of the single market, does the Commission intend to review this regulatory gap?

2. Will it follow the lead of the US Food and Drug Administration and classify air purifiers as medical devices?

3. If not, what are its current intentions regarding these devices?