Question for written answer E-000332/2019
to the Commission
Rule 130
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Subject: Safety of consumers using medical products and devices

In recent years, the number of serious injuries and even fatal incidents caused by malfunctioning medical devices has grown dramatically. EU legislation to reduce such risks will therefore enter into force in May 2020. The new standards impose stricter certification and marketing authorisation requirements on manufacturers and on companies that test products.

There are more than 27 000 companies in the EU which produce around half a million different types of medical products that will have to be inspected in order to continue to be available on the European market. Manufacturers and companies testing medical products and devices claim that this process will be very difficult to carry out without harming companies and consumers. The scope and timing of the regulation therefore force them to use a special clause (designed to ensure that key products are not withdrawn from the market) to avoid certifying products under the new rules for up to five years. This position is understandable, as companies need to be given sufficient time to adapt to the new requirements. However, the health and life of Community citizens is also important.

In this connection, how does the Commission intend to carry out the planned testing procedures while ensuring that certain medical products and devices do not disappear from the market and, at the same time, that consumers are protected?