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	Are biological and chemical indicators medical devices (MDs) in Europe?	Created	17.11.2020	UK
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The European Medical Device Directive (MDD) has been replaced in 05/2021 by the European Medical Device Regulation (MDR).

Packaging materials and sealing machines are already and will remain defined as medical devices and require registration also in Europe already.

However, the status of biological and chemical indicators have not changed and will remain as a non-MD and does not require registration in Europe.

This was the status of the MDD and will remain in MDR for biological and chemical indicators. The discussion if biological and chemical indicators are MDs or not, was ongoing during the last 20 years and has been clarified in the so-called “borderline document” from the European Commission, which clearly defines that they are no MDs. If the borderline document is modified, the status of biological and chemical indicators could change, however, currently there is no initiative to change the content of the borderline document.

In the USA biological and chemical indicators are medical devices and require 510(k) registration. In several other countries the registration is also necessary, however, the requirements for registration differ from country to country.

A lot of countries do not differentiate between the registration of

- pharmaceuticals
- diagnostics
- medical devices

and send questionnaires with the same requirements for pharmaceuticals and diagnostics without differentiating between the 3 groups.

The GKE cleaning process monitoring indicators (CPI) are no medical devices in all countries and do not require any registration.