



Kazakhstan ratified protocols amending the Agreement on common principles and rules for circulation of medical devices within the EAEU

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If you are interested in additional information, please contact us.

Briefly

On 6 February 2023 the President signed the Law “On ratification of the Protocol on amendments to the Agreement on common principles and rules for circulation of medical devices (devices for the medical purposes and medical equipment) within the EAEU dated 23 December 2014” No. 191-VII ZRK (the “**Protocol 1**”) and the Law “On ratification of the Protocol on amendments to the Agreement on common principles and rules for circulation of medical devices (devices for the medical purposes and medical equipment) within the EAEU dated 23 December 2014” No. 192-VII ZRK (the “**Protocol 2**”).

In details

The Protocol 1 stipulates that medical devices registered under the national procedure may be freely released into circulation in the territory of a member state without re-registration under the EAEU, as well as the possibility of re-registration of a medical device (reissue of the document confirming the fact of registration), making changes in the registration documents of a medical device under the national procedure until 31 December 2026 (except for medical devices, in respect of which an indefinite document confirming the fact of registration was issued, and except for changes that require a new registration).

The Protocol 2 provides for the extension of the possibility of registration of medical devices under the national procedure until 31 December 2022.

Are you interested in this topic?

- We would be pleased to discuss with you the above amendments and how they can impact your business;
- We can analyze and implement possible steps to ensure compliance with the new requirements.

If you are interested in additional information, please contact PwC specialists working as part of a group serving your company, or to any of the persons listed.