

### Amendment to the General Health Law regarding medical devices

Mexico City, May 31, 2023

On May 10, 2023, the Decree that amends, adds and eliminates different articles of the General Health Law (the "Decree"), was published on the Official Gazette of the Federation. The Decree includes within the term "Medical Devices" the concepts of medical equipment, prosthesis, orthosis, functional supporters, diagnosis agents, dental inputs, surgical and care materials, and hygiene products.

The Decree also enables the Health Ministry (the "Ministry") to classify as Medical Device, any input that because of its characteristics and use, can be consider as such.

On the other hand, the manufacturing process for the surgical and care material and hygiene products is no longer bound by the regulation applicable to Medicines, but to the regulation of medical devices.

The Decree also recognizes into the General Health Law the low-risk medical devices, which shall not require a marketing authorization (before the Decree such medical devices were only recognized in secondary resolutions).

Finally, the Decree typifies conducts that are considered as crimes related with medical devices (applying the same standard as crimes related to medicines).

The Decree entered into force the next day of its publication and granted a 180 business days term to the Ministry for the issuance of the regulation required for the enforcement of the Decree. According to the Decree, the Ministry shall issue the guidelines under which it shall determine whether a product shall be considered as Medical Device or not. Furthermore, the Ministry shall keep updated the list of products that shall be considered as low-risk inputs that do not require medical devices.

\* \* \*



*This document is a summary for disclosure purposes only. It does not constitute an opinion and may not be used or quoted without our prior written permission. We assume no responsibility for the content, scope or use of this document. For any comments regarding it, please contact any partner of our firm.*

