June, 2023

TIMELINE FOR THE IMPLEMENTATION OF NEW OBLIGATIONS FOR TRACEABILITY OF MEDICAL DEVICES

On September 17, 2022, Exempt Decree No. 63 of the Ministry of Health was published in the Official Gazette, approving Technical Standard No. 226 of the Ministry of Health, which set forth the obligation to implement a data registration system that allows the traceability of medical devices when they are received by institutional healthcare providers.

The purpose of this regulation is to implement a data registration system –physical or electronic– for the traceability of medical devices that facilitates prompt identification in cases where they need to be immobilized, quarantined or recalled from the market due to safety events associated with their quality, performance, use, storage or conservation.

This regulation includes instructions to be followed by the institutional healthcare providers and, additionally, prescribes the minimum data that must be considered in their registries.

For reasons of good service, the enactment of these obligations was deferred according to the following schedule:

1. Obligation of institutional healthcare providers to require their suppliers to deliver medical devices with: (i) documentation stating the medical device status of the products; and (ii) to indicate the minimum traceability data specified in the technical standard. This obligation is in force and enforceable since **March 18, 2023**.

2. Requirement for all institutional healthcare providers that receive a medical device to do so when the products are accompanied by their respective guides or invoices including traceability data. It will come into force on **September 20, 2023**.

3. Obligation to keep a registry of data associated with the traceability of medical devices, distinguishing between:

    a. Facilities that are considered as institutional providers of open and closed healthcare, authorized as such by the Basic Technical Standard N°58/2006 of the Ministry of Health. The registration obligation will enter into force on **September 18, 2023**.

    b. Healthcare providers that only provide open health care, in accordance with Basic Technical Standard No. 58/2006 of the Ministry of Health. The registration obligation will enter into force on **September 18, 2025**.

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Consequently, currently it is only required that institutional providers inform the requirements to suppliers delivering medical devices with the corresponding documentation and traceability data determined in the technical standard.

Finally, in order to support the implementation of this technical standard and clarify any doubts –including deadlines– the Department of Healthcare Networks issued Ordinary N°C37554, which was addressed to the Superintendence of Health to supervise institutional healthcare providers and verify compliance with this regulation.

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