Panama: New storage and distribution regulations of medical devices and related products

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Recently the National Directorate of Medical Devices of the Ministry of Health of the Republic of Panama, adopted Resolution No. 007 of May 10, 2021, through which guidelines are adopted for the storage and distribution of medical devices and related products regulated by Law 90 of December 26, 2017.

One of the most relevant introductions of the regulation is the obligation that all commercial establishments that store medical devices and related products must have their warehouse and adapted administrative offices, in order to avoid any condition that affects the quality of these and the personnel safety. The regulation establishes the minimum requirements that each area of the establishment must have. Likewise, the minimum requirements or conditions that the vehicles used to transport medical devices and/or related products must have.

On the other hand, regarding documentation, it is important to note that the resolution establishes that annual internal audits, which must include at least results, evaluation, conclusions and corrective actions, must be documented, kept and be available for review by the authority for a minimum of 7 years. These must be signed by the Regent of Medical Devices and Legal Representative. In the case of cold chain temperature records, in particular, and any other document that details the record of the activities requested in the resolution, they must be kept and be available for a minimum period of 3 years.

For more information, you can contact **Analiz Nieto**.

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