

ISP PUBLISHES INFORMATIONAL MATERIAL NO. ON THE SANITARY CONTROL OF MEDICAL DEVICES INCLUDED UNDER EXEMPT DECREE NO. 25/2026

On October 2, 2026, the Chilean Public Health Institute ("ISP") announced the publication of "Informational Material No. 1 on Exempt Decree No. 25/2026," prepared by its National Medical Devices Agency Department to facilitate implementation of the regulation.

The decree, published in the Official Gazette on March 19, 2026, brought certain medical devices and in vitro diagnostic medical devices under the sanitary control regime established in Article 111 of the Chilean Health Code. The material aims to address technical questions regarding its scope and help companies identify the products covered by it.

Key aspects:

- Category-based matrix: organizes the medical devices and in vitro diagnostic medical devices covered by the Decree by category and summarizes the intended use of each category.
- Scope: provides non-exhaustive descriptive examples of products considered to fall within or outside the scope of the decree, to help assess whether a product is covered.
- Risk class and validity period: specifies both for each category.

The ISP indicated that this is the first release and that it will continue to prepare informational materials on the implementation of the decree.

[Informational Material No. 1 on Exempt Decree No. 25/2026 \(in Spanish\)](#)

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