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MINSAL INCORPORATES NEW MEDICAL DEVICES INTO SANITARY CONTROL REGIME

The Chilean Ministry of Health (MINSAL), through Exempt Decree No. 25, has incorporated a broad range of medical devices (MD) and in vitro diagnostic medical devices (IVDMD) into the sanitary control regime established under Article 111 of the Health Code, making it mandatory to obtain a marketing authorization for their manufacturing, importation, commercialization, and distribution.

This regulatory update prioritizes devices with the highest clinical impact and sanitary risk, based on criteria such as their critical nature, risk classification (Classes III and IV for MD, Classes C and D for IVDMD), their use in ministerial programs, participation in quality evaluation programs, and the existence of adverse event reports in the technovigilance system.

Among the devices incorporated into the sanitary control regime are:

•**IVDMD:** Tests for Helicobacter pylori, Human Papillomavirus (HPV), respiratory viruses (such as Influenza and SARS-CoV-2), glucose monitoring systems, and pregnancy tests.
•**MD Class IV (high risk):** Implantable defibrillators and pacemakers, stents, cardiovascular catheters, cardiac valves, cochlear implants, hip endoprostheses, breast implants and expanders, and intrauterine devices (IUDs).
•**MD Class III:** Insulin infusion pumps, blood bags, radiotherapy and brachytherapy equipment, mammography systems, CT scanners, hemodialysis equipment, intraocular lenses, mechanical ventilators, and electrosurgical units.
•**MD Class II:** Continuous glucose monitoring systems, automatic sphygmomanometers, CPAP/BPAP devices, and sterilization equipment.
•**Medical Software (SaMD):** Software for processing, analysis, and planning of oncological imaging.

To be marketed, these devices must obtain marketing authorization from the Public Health Institute (ISP), which will act as the conformity

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assessment body. Applicants must provide documentary evidence demonstrating compliance with applicable technical standards (including NCh and ISO), ensuring safety, quality, and performance. Any significant modification in design, manufacturing, or intended use will require a new sanitary registration.

Regarding implementation timelines:

- **24 months:** For high-risk and critical implantable devices.
- **36 months:** For the remaining devices.

Additionally, the decree allows manufacturers and importers to voluntarily initiate the conformity assessment process before the mandatory deadlines, once the ISP issues the corresponding technical guidelines, which must occur within a maximum period of 12 months.

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