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MINSAL LAUNCHES PUBLIC CONSULTATION TO INCORPORATE NEW MEDICAL DEVICES INTO THE SANITARY CONTROL REGIME

On November 13, 2025, based on Article 111 of the Chilean Health Code and Supreme Decree No. 825 of 1998 of the Ministry of Health —which approved the Regulations for the Control of Medical Products and Devices— the Ministry of Health ("MINSAL") launched a public consultation to incorporate new medical devices ("MD") and in vitro diagnostic medical devices ("IVDMD") into the mandatory sanitary control regime.

The proposal covers the inclusion of 39 medical devices in total under mandatory control, including:

• IVDMD: tests for the detection of Helicobacter pylori, HPV, respiratory viruses, glucose monitoring systems, and pregnancy tests.
• Class IV MD: defibrillators, pacemakers, stents, cardiovascular catheters, heart valves, cochlear implants, hip endoprostheses, breast implants and expanders, intrauterine devices (IUDs), among others.
• Class III MD: insulin pumps, blood bags, radiotherapy equipment, mammography units, CT scanners, hemodialysis machines, intraocular lenses, mechanical ventilators, electrosurgical units, among others.
• Class II MD: continuous glucose monitoring systems, sphygmomanometers, CPAP/BPAP devices, steam sterilization equipment, among others.
• Software as a Medical Device (SaMD): software used for oncology imaging analysis and treatment planning.

Selection criteria

According to the consultation documents, the selection of MD and IVDMD was based on, among others, the following criteria:

• MD/IVDMD classified as critical under Ord. No. C37/No. 73 of the Ministry of Health.

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• MD risk classes II, III, and IV (with priority given to classes III and IV).
• IVDMD risk classes B, C, and D (with priority given to classes C and D).
• MD/IVDMD used in services associated with Ministerial Plans and Programs.
• MD included in quality assessment programs for radiotherapy, mammography, and nuclear medicine.

Records of adverse events reported to the Technovigilance system.

Conformity assessment and sanitary registration

To manufacture, import, market, or distribute in Chile the medical devices covered by the proposal, manufacturers or importers must provide evidence of conformity in accordance with the specific national or international technical standards set forth in the proposal.

Conformity verification will be granted by the Public Health Institute ("ISP"), certifying that the device meets applicable quality, safety, and performance standards.

The proposal further establishes that, if the device undergoes a significant modification affecting its quality, safety, or performance, the holder must request a new sanitary registration.

Implementation timeline

From the date of publication of the decree in the Official Gazette, the proposal provides for the following implementation periods of the sanitary control regime:

•**24 months** for high-risk implantable devices, such as pacemakers, stents, heart valves, implants, IUDs, insulin pumps, among others.
•**36 months** for the remaining devices, including imaging equipment, hemodialysis machines, mechanical ventilators, software, diagnostic tests, sterilization equipment, among others.

In addition, a transitional provision allows manufacturers and importers to voluntarily submit their devices for conformity verification before the decree enters into force, thereby anticipating compliance with these requirements.

Recommendations

In light of this public consultation, it is advisable that:

• Manufacturers and importers assess whether their devices are included among the 39 MD/IVDMD covered by the proposal and analyze the related regulatory and operational impacts.
• Companies start preparing the required technical and conformity documentation in advance for submission to the ISP.
• Stakeholders evaluate the benefits of early, voluntary conformity verification, particularly for high-risk devices.

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