Galicia

Life Sciences Update

New NOM-137-SSA1-2025, Labelling of Medical Devices

Mexico City, May 28, 2026

On May 19, 2026, the Official Mexican Standard "NOM-137-SSA1-2025, Labelling of Medical Devices" (the "NOM-137-2025") was published in the Federal Official Gazette ("DOF"), which amends and cancels the "NOM-137-SSA1-2008, Labelling of Medical Devices" (the "NOM-137-2008").

The NOM-137-2025 is mandatory for establishments engaged in the manufacture, conditioning, distribution or importation of medical devices for their commercialization or supply in Mexico. Amongst its main contributions, it incorporates proper use and traceability as regulatory objectives, positions labelling as an active safety tool and requires that labelling elements be developed and evaluated on the basis of risk management.

It expressly recognizes that medical devices may be used directly by patients and by the general public, and therefore requires that health information and instructions for use be drafted in terms understandable to the intended user, supplemented with drawings and diagrams, and indicate the circumstances under which the user should consult a healthcare professional.

Specific requirements are established for the labelling of software as a medical device ("SaMD"), including the obligation to provide a unique identifier (version, revision level or release date) accessible to the user. For software without a physical form or packaging, labelling may be made available electronically, provided that a means is incorporated to allow the user to easily access the information through the software itself, a website or other means. To this end, the use of technologies such as RFID, barcodes, QR codes or similar is permitted, which may physically accompany the device or direct the user to a website or electronic platform. The information provided through such means may not replace or contradict that which has been approved in the marketing authorization. It should be noted that the definition of SaMD contained in NOM-137-2025 is consistent with that set out in the "NOM-241-SSA1-2025, Good Manufacturing Practices for Medical Devices".

The labelling requirements for in vitro diagnostic agents are significantly expanded, requiring that instructions for use include the characteristics of analytical performance (precision, accuracy, sensitivity, specificity) and, as applicable, of clinical performance (diagnostic sensitivity and specificity, predictive values, amongst others). Additionally, the NOM-137-2025 recognizes the category of in vitro diagnostic agents for self-testing, establishing differentiated communication obligations directed at users without formal training.

Whilst the NOM-137-2025 substantially maintains the labelling requirements set out in the NOM-137-2008, it introduces the following relevant changes: (i) labelling elements must be developed and evaluated on the basis of risk management; (ii) the label of all medical devices must include the date of manufacture, which may be incorporated as part of the lot or serial number, provided that it is clearly identifiable; (iii) the label of all medical devices must include the catalogue number, model, reference or version, whereas the NOM-137-2008 only required this for in vitro diagnostic agents on an optional basis; (iv) a specific section is incorporated requiring that residual risks derived from risk management be included in the labelling, as well as information on materials, substances and manufacturing residues that pose a risk to health; (v) the labelling must include guidance on whom the patient or user should contact in the event of an incident or adverse incident, including the competent authority; (vi) mandatory warnings are significantly expanded to cover carcinogenic, mutagenic and reprotoxic substances, nanomaterials, latex, human blood or plasma derivatives, incorporated drugs, as well as exposure to magnetic, electromagnetic and electrostatic discharge fields; (vii) specific labelling requirements are established for reusable devices, including cleaning, disinfection and sterilization procedures and the number of possible reuses; (viii) information on the expected useful life of the device, precautions in the event of changes in its performance and applicable end-of-life measures must be included; and (ix) detailed instructions on the final disposal of the medical device are required, covering infection, environmental and physical hazards.

NOM-137-2025 shall enter into force 360 calendar days after its publication in the DOF. From the date it enters into force, holders of marketing authorizations shall have a period of 180 calendar days to exhaust existing stocks of packaging materials and finished products whose labelling cannot be modified in accordance with the new requirements. Likewise, as of that date, NOM-137-2008, published on December 12, 2008, shall cease to have effect.

* * *