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ISP PUBLISHES GUIDELINE ON AUTHORIZATION FOR THE PROVISIONAL USE OF MEDICAL DEVICES IN CLINICAL INVESTIGATIONS INVOLVING HUMAN SUBJECTS

Through Exempt Resolution No. E5435/2026, the Public Health Institute of Chile ("ISP") approved the "Guideline on Authorization for the Provisional Use of Medical Devices ("MDs") in Clinical Investigations Involving Human Subjects", prepared by its National Medical Devices Agency Department ("ANDIM").

The Guideline distinguishes between clinical investigations that will be subject to an authorization procedure for the provisional use of the investigational MD, under Article 111 A of the Sanitary Code, and those that will be subject to a provisional use notification regime (e.g., Class I and II MDs, and certain observational and post-market investigations, as set out in the Guideline). Its main objective is to provide guidance to medical device manufacturers and importers, sponsors, contract research organizations, investigators and research centers on the applicable requirements and the documentation needed to submit an application for authorization for the provisional use of MDs in clinical investigations, and a notification, respectively.

Scope of the Guideline

The Guideline covers clinical investigations conducted wholly or partly in Chile, at different stages of clinical development. It includes investigations intended to evaluate new devices, or new indications, new intended uses and significant changes to devices already on the market. In vitro diagnostic medical devices are expressly excluded from its scope.

Submission of documentation and follow-up

The procedure involves submitting the relevant ANDIM form and a single dossier containing documents such as the clinical investigation plan, the investigator's brochure, the conformity

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verification document, the favorable report of a scientific ethics committee (“SEC”), among others.

It also governs the validity and extension of authorizations, amendments thereto, and the grounds for denial or cancellation. It thus provides a reference framework for preparing applications and managing changes that may arise during a clinical investigation.

Publication of the Guideline in the Official Gazette is still pending, as the publication of the corresponding official code (prestación) on the ISP website.

The resolution and the approved Guideline are available at the following link: Exempt Resolution No. E5435/2026.

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