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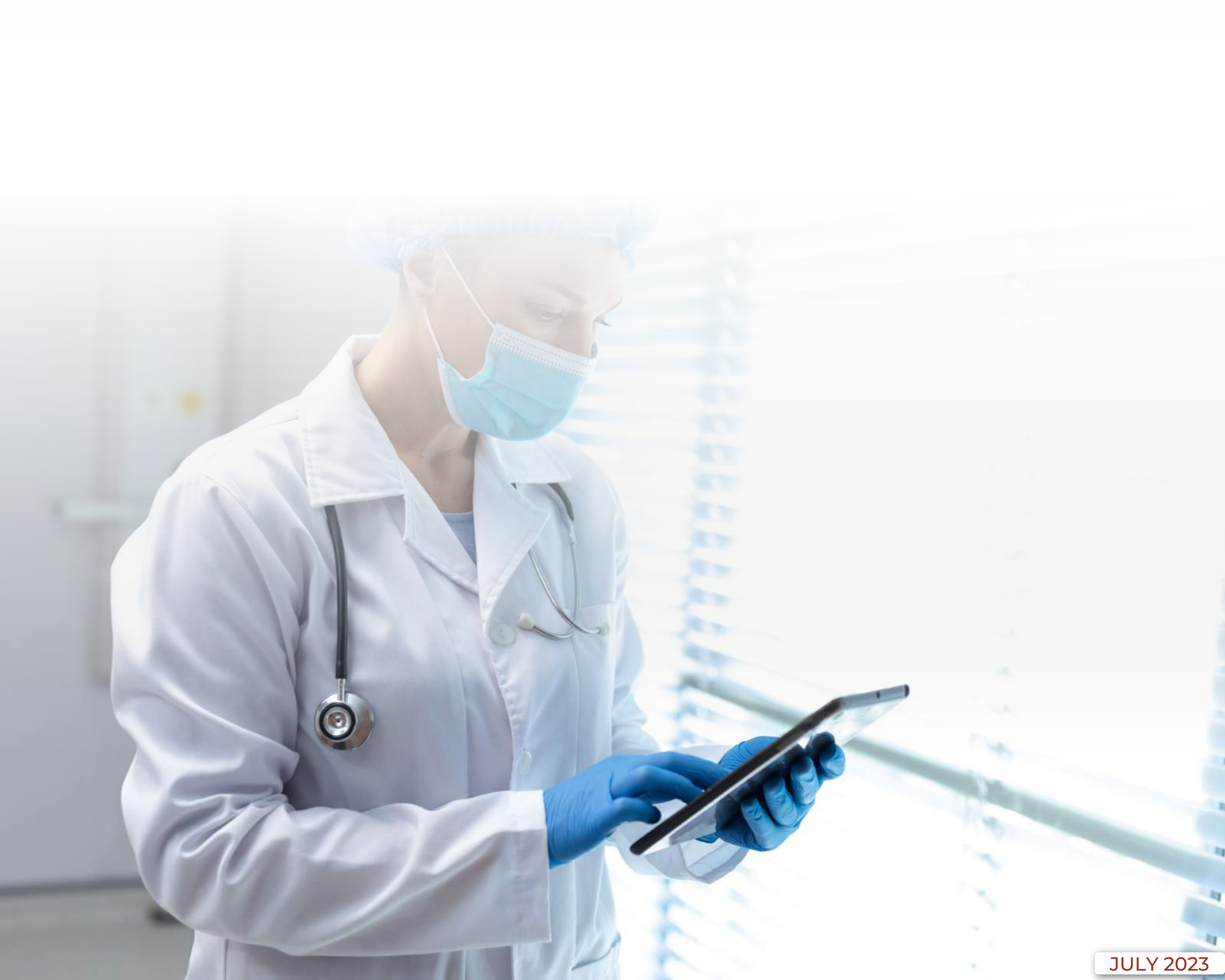
REGULATION OF SOFTWARE AS A MEDICAL DEVICE IN MEXICO



JULY 2023

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Introduction

Technological advancement has enabled the evolution of medicine and digital health. In Mexico, on May 10th, an announcement was published in the Official Journal of the Federation marking a milestone in the regulation of medical devices. It is the Announcement regarding the sale of the Supplement for Medical Devices 5.0 of the Mexican Pharmacopoeia (FEUM), which includes the regulatory appendix on Software as a Medical Device (SaMD).

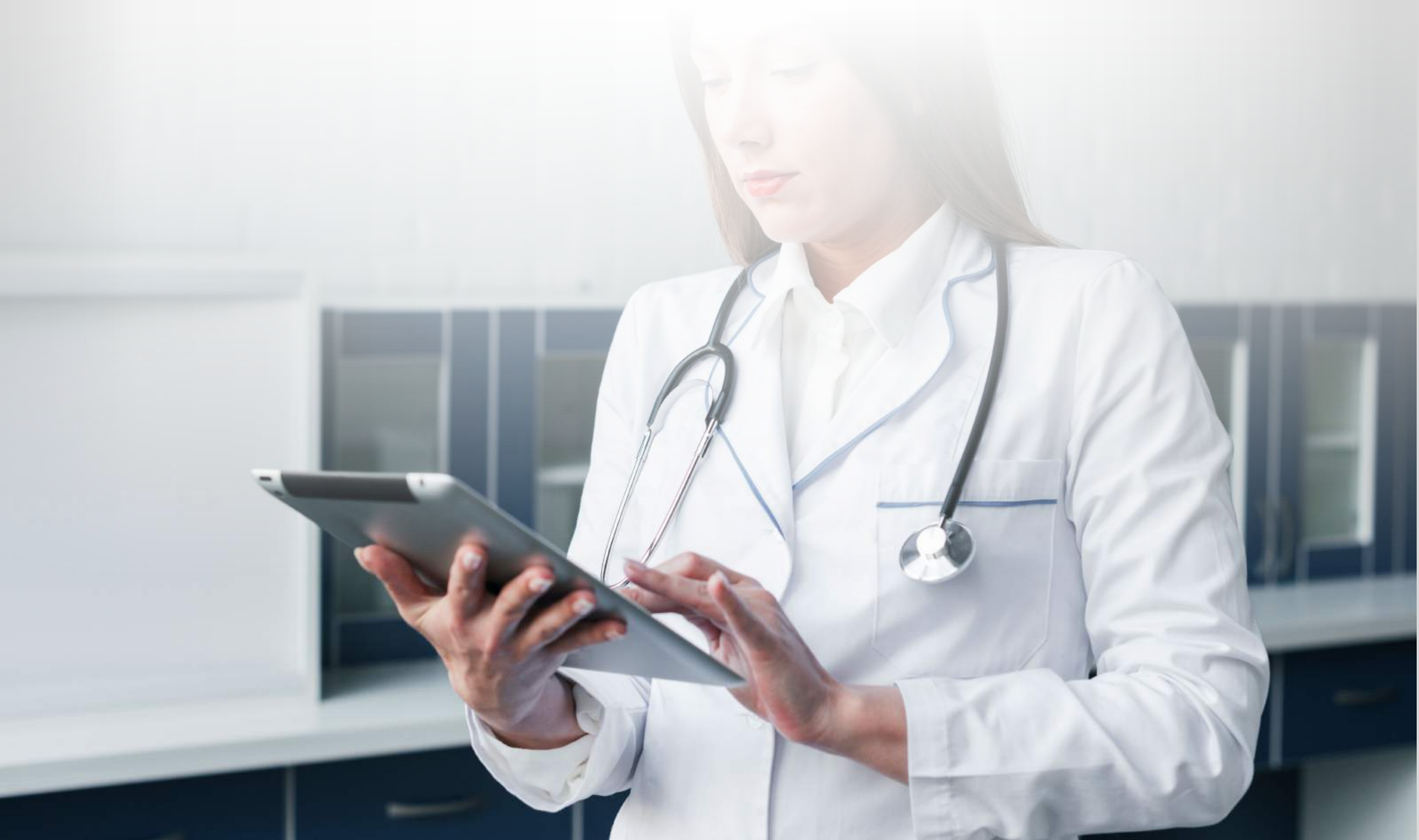
The digital health industry has experienced exponential growth in recent years, with the emergence of devices and mobile applications aimed at improving healthcare and facilitating access to medical services. This is of great importance, as the health authority, together with the industry and academia, worked tirelessly to define the regulatory framework for these types of devices, which have been marketed in our country for several years without clarity regarding their health regulation, until now.

WHAT IS THE OBJECTIVE?

The objective of **Appendix X. Software as a Medical Device,** is to establish the following:

- Harmonized definitions for the correct context of SaMD.
- General and specific considerations throughout its life cycle: requirements, design, development, testing, maintenance, and use.
- Common understanding of clinical evaluation and the principles for demonstrating safety and performance.

Additionally, some **criteria are established to determine its classification**, which must be applied in conjunction with what is described in Rule 16 of Appendix II. Criteria for the classification of medical devices based on their level of health risk, from the same supplement of the FEUM. With this, the obligation to **request health registration** with the same requirements described in the Agreement on procedures and services, as well as in Appendix III. Guidelines for obtaining the health registration of a medical device, its modifications, and extensions, is recognized.

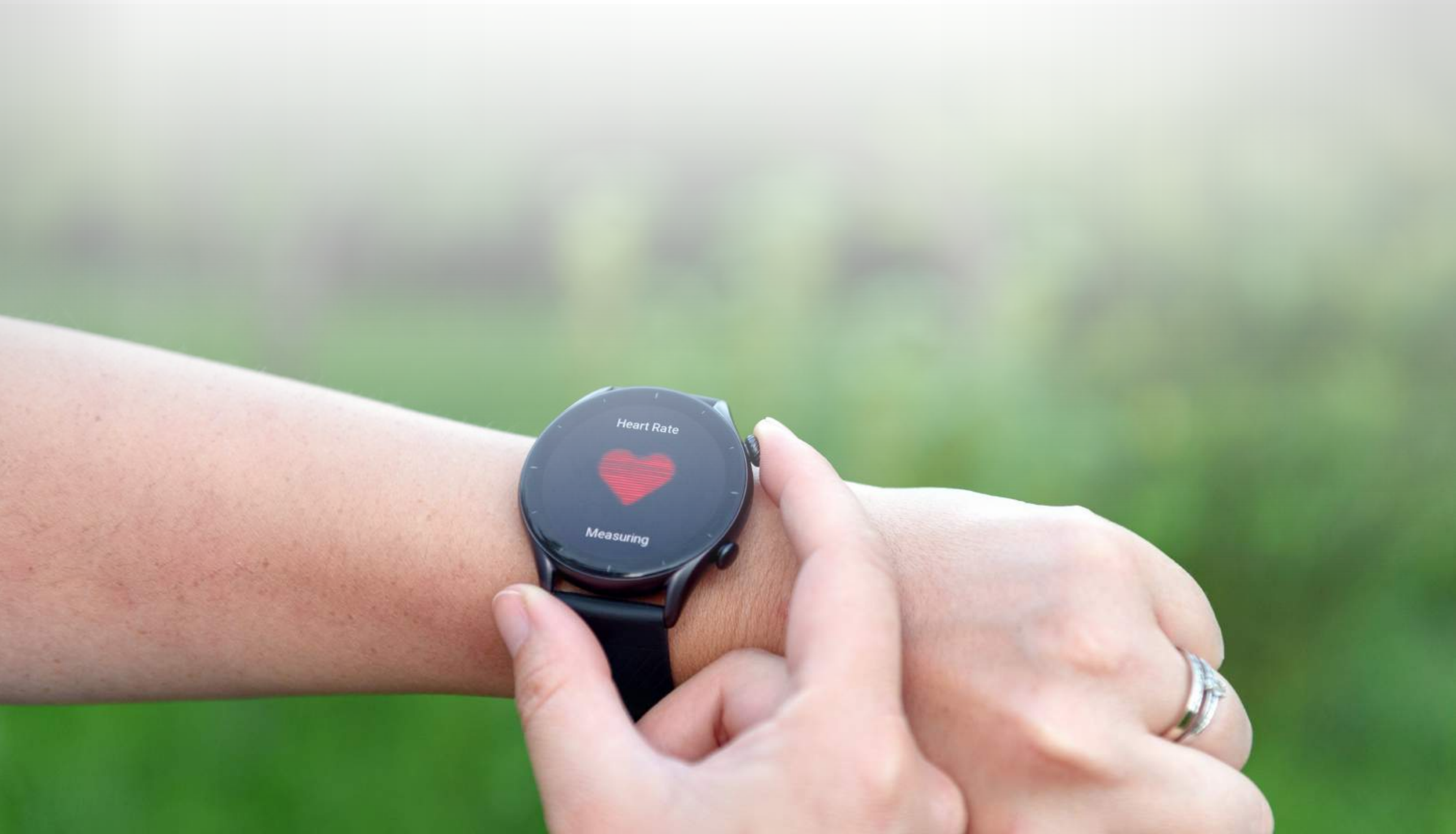


WHAT ARE THE REQUIREMENTS?

In general, the requirements are as follows:

ADMINISTRATIVE-LEGAL REQUIREMENTS	TECHNICAL REQUIREMENTS
Application form Legal accreditation Payment of fees Notice of operation and responsible health officer Labeling design Letter of representation (if applicable) Good Manufacturing Practices certificate (GMP) Certificate of Free Sale (CLV) Software license Among others	Software validation Clinical evaluation Performance evaluations Among others

Within the SaMD universe, there are mobile applications. In item 7 of Appendix X, the regulatory approach for these **medical apps** is described, as well as those considered subject to health control.



Some examples are:

- Mobile apps that are an extension of one or more medical devices through the connection of these devices with the intention of controlling the device or being used in the active monitoring of the patient: those that provide the ability to control the inflation and deflation of a sphygmomanometer, or those that control the administration of insulin from a pump.

- Mobile apps that transform the mobile platform into a regulated medical device through the use of accessories, screens, or sensors by including functionalities similar to those of current regulated medical devices. Examples of these apps include the glucose strip reader on a mobile platform that functions as a glucometer; the connection of electrocardiograph (ECG) electrodes to a mobile platform to measure, store, and display ECG signals, among others.

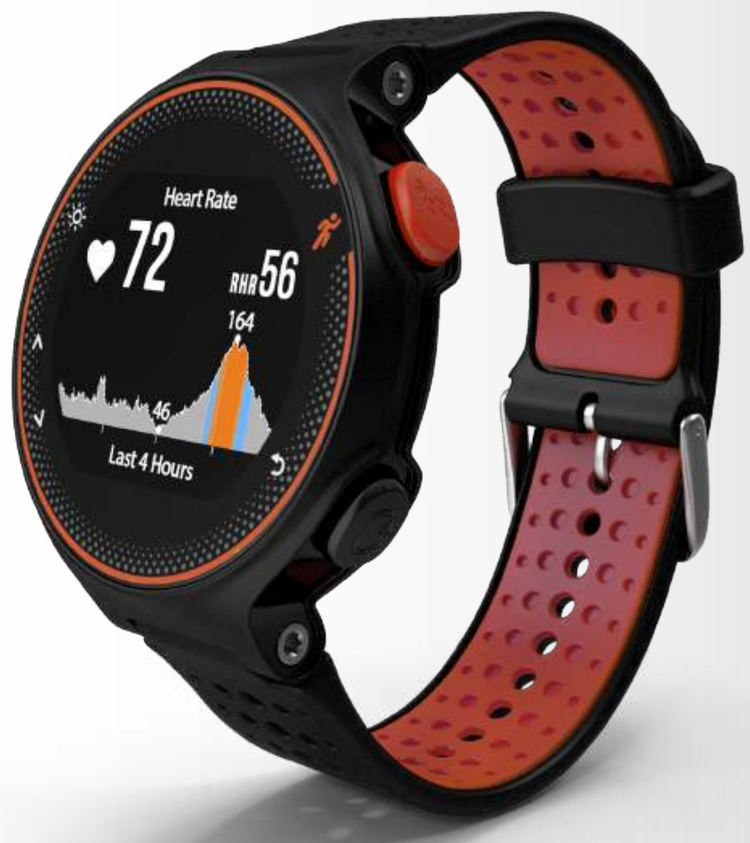
- Mobile apps that become a regulated medical device (software) by performing specific analyses on the patient, providing a diagnosis, treatment, or specific recommendations: apps that use specific patient parameters to calculate the dose or create a dosing plan for radiation therapy.

Important

For some mobile apps, **the authority may exercise discretion** in the application of the regulation, so it is advisable to request a prior consultation to determine whether the SaMD we intend to register is subject to this authorization or not.

WHEN DOES IT COME INTO EFFECT?

The Supplement will come into effect as of July 10, 2023, and it is important that the involved parties, including the health authority, the industry, and academia, continue working together to keep the regulation up to date and ensure public health protection in the context of rapid technological evolution and the emergence of new medical devices.



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