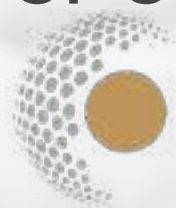


SIMPLIFIED GUIDE

REGISTRATION OR MODIFICATION OF OPERATING NOTICES IN



DIGIPRIS

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SIMPLIFIED GUIDE FOR THE REGISTRATION OR MODIFICATION OF OPERATING NOTICES IN **DIGIPRIS**

According to Articles 47 and 200 Bis of the General Health Law, all establishments that do not require health authorization and that carry out activities related to products and services under health control will be required to process an operating notice.

Currently, the processing of these notices is done through the **COFEPRIS** website, in the 'Self-Managed Procedures' section in **DIGIPRIS**.

Below, we present the simplified steps to successfully request your notice:



REGISTRATION

First, you must register your company as a legal entity, or alternatively, complete the **registration** as an individual, depending on the case, on the following platform: **DIGIPRIS**: <https://digipris.cofepris.gob.mx/registro> For this, you must have the corresponding e-signature. Subsequently, both the legal representative and the health officer of the establishment must register as individuals, also using their e-signatures.

The registration of your company, legal representative, and health officer will later allow you to access the procedure for the Operating Notice directly with your e-signature, where your data will be automatically downloaded.



Selecciónale la persona que desea registrar:

☒ Persona física ☐ Persona moral

Por favor, introduce tu certificado de firma, compuesto por dos archivos: .cer y .key.
Serán validados por el sistema:

Certificado (.cer)[*] ⓘ

Llave privada (.key)[*] ⓘ

Contraseña de clave privada[*] ⓘ

Antes de comenzar el registro, revisa nuestro aviso de privacidad:
☐ Acepto el Aviso de Privacidad[*]

* Campos obligatorios



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ENROLLMENT

To **register** an Operating Notice, you must log in with the e-signature of the company or individual that you registered in the previous step, as the data will automatically link to begin the registration process.



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HOMOClave

Subsequently, you will need to select the **homoclave** and modality according to the type and activities of your establishment.

Avisos

Insumos de la salud

Servicios de salud

Productos y servicios

Salud ambiental

Aviso de funcionamiento y responsable sanitario del establecimiento de insumos para la salud. Modalidad A.- Fábrica de Dispositivos Médicos o Remedios Herbolarios.

Aviso de Funcionamiento y respoinsable sanitario del establecimiento de insumos para la salud. Modalidad B.- Almacén de Deposito y/o Distribución de Dispositivos Médicos o Remedios Herbolarios o Medicamentos No Controlados o Materia Prima para Medicamentos No Controlados.

Aviso de funcionamiento y responsable sanitario del establecimiento de insumos para la salud. Modalidad C.- Distribución de Medicamentos (como Representante Legal en México de una Empresa en el Extranjero).

Aviso de funcionamiento y responsable sanitario del establecimiento de insumos para la salud. Modalidad D.- Farmacia Alopática o Farmacia Homeopática (Sin Preparación de Especialidades Farmacéuticas) o Botica.

Aviso de funcionamiento y responsable sanitario del establecimiento de insumos para la salud. Modalidad E.- Comercio al pormenor de Disositivos Médicos o Remedios Herbolarios.



OWNER INFORMATION

In the following steps or tabs, you must provide **information about the owner**, establishment, health officer, and the product or service. It is very important that, in the case of being a legal entity, you must have the notarized power of attorney or the articles of incorporation of the legal representative, as well as their official identification digitized, as both will be documents you need to upload when entering the owner's and establishment's information.

Homoclave: COFEPRIS-05-006-B

Propietario
Establecimiento
Responsable sanitario
Producto o servicio
Protesta de veracidad
Firmar trámite

Establecimiento

Paso 1 Datos → Paso 2 Actividad → Paso 3 Representantes → Paso 4 Verificación → [Checkmark]

¡Muy bien!
Los datos del establecimiento fueron completados.
Continúa con el registro de productos y servicios.

Continuar



SIGNATURE

Once you have completed filling out all the information, both the health officer and the legal representative will receive an email with a request to **sign** the application. They must log in to their account using their e-signature on the DIGIPRIS platform, where they will see a pending procedure to sign. It is very important that the health officer signs first, followed by the legal representative.



OPERATING NOTICE

Finally, the Operating Notice will be sent by email to the legal representative and can also be downloaded directly from the company or individual's session on DIGIPRIS.

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MODIFICATION

For the case of modifying an Operating Notice, the steps are the same as for the registration. However, upon logging in with the e-signature of the company or individual, you must select the option 'Modification, Suspension, or Cancellation,' where the data of the establishment previously registered in COFEPRIS will automatically appear. It does not matter if the Operating Notice was originally registered physically before the digital modality; your establishment's data should already appear on the platform. If you encounter any issues at this point, you can send an email to digipris@cofepris.gob.mx.

Aviso de modificación o baja al aviso de funcionamiento y/o responsable sanitario del establecimiento de insumos para la salud
(COFEPRIS-05-007-B)

Aviso de funcionamiento y de responsable sanitario del establecimiento de insumos para la salud. Modalidad B.-Almacén de Depósito y/o Distribución de Dispositivos Médicos, o Remedios Herbolarios o Medicamentos No Controlados o Materia Prima para Medicamentos No Controlados.

Para iniciar el trámite es necesario que selecciones uno de tus establecimientos

Establecimientos registrados

1 establecimiento(s)

Comercializadora Buenos Aires S.A.
Unidad de Círculo de Vigilancia, Barrio Sagel
Blvd. de la Cruz, Calle San Felipe 152. TL. 05530

Cancelar Modificar

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MODIFICATION NOTICE

Once you access the platform, you will be able to modify or cancel the data you require in your application.

Aviso de modificación o baja al aviso de funcionamiento y/o responsable sanitario del establecimiento de insumos para la salud
(COFEPRIS-05-007-B)

Aviso de funcionamiento y de responsable sanitario del establecimiento de insumos para la salud. Modalidad B.-Almacén de Depósito y/o Distribución de Dispositivos Médicos, o Remedios Herbolarios o Medicamentos No Controlados o Materia Prima para Medicamentos No Controlados.

Descargar aviso

Cancelar baja Suspender Modificar

Propietario

Persona moral:

Denominación o razón Social: INNOVACION VALOR Y DESARROLLO SA.
RFC: IVD020810022

Representante legal:



EXTENSION

If for any reason you are unable to complete the registration or modification process on the platform, the system grants you one calendar month to finalize the procedure. If you do not complete it, it will be automatically deleted from the platform.



DOWNLOAD

“Finally, the procedures you have completed can be downloaded at any time from your account.



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