

1- DATOS DEL EVENTO		
1	Denominación	26 th Session of the International Medical Device Regulators Forum (IMDRF)
2	Organización	U.S. Food and Drug Administration (FDA)
	Objetivo	✓ Presentar la solicitud de aplicación de DINAVISA como Miembro Afiliado en IMDRF y participar de los Grupos de Trabajo de IMDRF sobre Dispositivos Médicos.
3	Fecha de realización	16/09/2024 al 20/09/2024
4	Lugar (ciudad/país)	Seattle, Washington.
5	Lugar Hospedaje	A confirmar
2- Datos de la persona autorizada		
1	Nombre y Apellido	Alison Rocio Iglesias Valdez
2	Cedula de Identidad	4.190.253
3	Cargo	Directora.
4	Entidad/Dependencia donde presta servicios	Dirección de Registro de Dispositivos Médicos y Odontológicos.
3- Costos		
1	Fecha de salida y Fecha de retorno	Salida 15/09/2024 Retorno 21/09/2024
2	Costo del Pasaje	A confirmar DINAVISA
3	Viatico	A confirmar DINAVISA
4	Costo de refuerzo de viatico	En caso necesario DINAVISA
5	Costo total del viaje	A determinar
4- Pertinencia		
1	Correspondencia entre el objetivo del evento y las funciones desempeñadas por el solicitante	La Dirección de Registro de Dispositivos Médicos y Odontológicos es la dependencia técnica encargada del Registro de Dispositivos Médicos a través del desarrollo y aplicación de normativas aplicables a dichos productos, por lo cual solicita a IMDRF formar parte de la membresía como Afiliado y participar de los Foros además de los grupos de trabajo con el objetivo de llevar a cabo la regulación de los Dispositivos Médicos acorde a otras Autoridades Regulatorias de Referencia Internacionales que forman parte del IMDRF y de esa manera garantizar el uso de dispositivos médicos de calidad, seguridad y eficacia en el Paraguay.
2	Carácter de la Participación	Participante
3	Resolución que Autoriza el Viaje	Resolución DINAVISA N° 175 /24 de Fecha 23 de julio del 2024
5- Información complementaria		
1	Adjuntar el programa de actividad del evento	

Q.F. Alison R. Iglesias V.
 Directora Interina
 Dir. de Reg. Dispositivos Médicos y Odontológicos - DINAVISA



July 28, 2024

Qca. Fca. Alison Rocío Iglesias
Director of the Directorate of Medical and Dental Devices
La Dirección Nacional de Vigilancia Sanitaria (DINAVISA)
Via: alisonrocioglesiasvaldez@gmail.com, secretariageneral@dinavisa.gov.py,
relaciones.internacionales@dinavisa.gov.py

Subject: Affiliate applicant invitation to 26th Session of IMDRF

Dear Qca. Fca. Alison Rocío Iglesias:

The U.S. Food and Drug Administration, in its role as Chair and Secretariat of the International Medical Device Regulators Forum (IMDRF) in 2024, acknowledges that DINAVISA has submitted an application for Affiliate membership in IMDRF. As such, we write to invite you to attend the 26th Session of IMDRF in Seattle, Washington, from 16-19 September 2024.

Meeting Details

The IMDRF community aspires to positively impact public health by aligning on medical device policies, standards, and practices. In person meetings of the Forum gather regulators, industry, academic, and key stakeholders to move IMDRF toward this vision. The 26th Session will build on the momentum and ideas of the prior meeting held in Washington, DC, in March 2024. This meeting will also highlight important new developments and welcome new members to provide insights.

The meeting will be held at the Seattle Marriott Waterfront located at 2100 Alaskan Way, Seattle, Washington, USA, 98121. It will begin the morning of 16 September 2024 and conclude the afternoon of 20 September 2024. Although we highly encourage your participation in person, a virtual option to livestream the meeting will be available.

A detailed agenda will soon be available on the website for the 26th Session at: <https://events.espinc-usa.com/imdrf092024/agenda>. The general format of the meeting is below.

Date		
Day 1	Monday 16 September, 2024	Joint IMDRF Stakeholder Workshop with DITTA and GMTA
Day 2	Tuesday 17 September, 2024	IMDRF Stakeholder Open Forum
Day 3	Wednesday 18 September, 2024	MC Meeting Open Session
Day 4	Thursday 19 September, 2024	MC Meeting Closed Session, including Affiliate applicants
Day 5	Friday 20 March, 2024	MC Meeting Closed Session



Q.F. Alison R. Iglesias V.
Directora Interina
Dir. de Reg. Dispositivos Médicos y Odontológicos - DINAVISA



U.S. FOOD & DRUG
ADMINISTRATION



IMDRF

Registration Open

To secure your spot for days 1-4 of the IMDRF meeting, **please register at** <https://events.espinc-usa.com/imdrf092024/begin> **by August 26, 2024.**

Travel Arrangements

This invitation is offered with the understanding that all expenditures are to be provided by your government, including costs for travel, housing, transportation, and related logistics for your visit. While we cannot assist in the process of obtaining a Visa from your government to attend this meeting, please reach out if you require additional information in support of your application.

For your convenience, we have secured special rates at the meeting venue and nearby hotels. Please refer to the meeting website at <https://events.espinc-usa.com/imdrf092024/hotels> for details on reserving a hotel and helpful information about Seattle, Washington.

If you have any questions, please contact the Secretariat at IMDRF2024@fda.hhs.gov.

We look forward to welcoming you in September to advance the mission of IMDRF.

Sincerely,

Jeff Shuren, M.D., J.D.
Chair, IMDRF 2024
Director, Center for Devices & Radiological Health (CDRH)
U.S. Food and Drug Administration (FDA)



Q.F. Alison B. Iglesias V.
Directora Interina
Dir. de Reg. Dispositivos Médicos y Odontológicos - DINAVIS