



November 2, 2023

Amina Hayat Achaibou Taright
Director of International Affairs
Comisión Federal para la Protección Contra Riesgos Sanitarios (COFEPRIS),
México

Dear Ms. Amina Hayat Achaibou Taright,

I am writing to you on behalf of the Medical Device Single Audit Program, Regulatory Authority Council (MDSAP RAC) and as the RAC Chair. The application of COFEPRIS to become an affiliate member of the MDSAP was discussed at a recent MDSAP RAC meeting on October 24, 2023.

The RAC has unanimously agreed to recognize COFEPRIS's request for affiliate membership as you have adequately demonstrated the understanding and utilization of the program.

Congratulations on your membership and we look forward to your participation and utilization of the MDSAP audit reports and/or MDSAP certificates in the context of the evaluation of a medical device manufacturer's quality management system. The MDSAP consortium intends to promptly publish COFEPRIS participation as an affiliate member on its website. Please refer to MDSAP P0003 for Affiliate Membership rights and obligations. As part of the fulfillment of Affiliate Membership obligations, COFEPRIS needs to report annually its utilization of the MDSAP report and/or MDSAP certificates to the RAC. This report should include information on how the MDSAP reports or certificates were employed, along with specific case numbers. The first report would be due on November 1, 2024.

Sincerely,

Kenichi Ishibashi

Kenichi Ishibashi
Chair
Regulatory Authority Council
Medical Device Single Audit Program