

Bob Ogden

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(Customer No. 1432169), Metris Instruments East, LLC- New 2020 Medical Device **Establishment Registration**

2 messages

Medical Devices <medicaldevices@registrarcorp.com> To: bobogden2005@gmail.com

Fri, Apr 10, 2020 at 4:21 PM

Good Day,

This email confirms that we successfully completed your firm's Medical Device Establishment Registration with the U.S. Food and Drug Administration (FDA). Your device establishment has been registered with the FDA and payment of the user fee has been submitted on behalf of your establishment for the 2020 fiscal year and will expire on December 31,

The attached document contains your establishment registration confirmation and if applicable device listing information for your records. Please reference your Owner Operator Number along with the device listing numbers if applicable on all shipping invoices.

U.S. FDA Assigned Owner/Operator Number: 10068952

Registration Number: Not Yet Assigned by FDA (may take 90 days, possibly longer)

Registrar Corp will issue Certificates of Registration after the FDA Establishment Registration and Device Listing Database is updated. Please allow 2-3 weeks for those updates to occur. Certificates of registration are issued by Registrar Corp as third-party verification for customers and suppliers that your establishment is registered, and the device in question is listed, with the FDA. The FDA does not issue or recognize certificates of registration.

Please note that your shipments to the USA may be detained if your FDA registration is not updated to reflect your current manufacturers, importers, and proprietary brand names. As your firm's Official Correspondent and/or U.S. Agent; Registrar Corp will assist you with these required updates at no additional cost.

As your firm's Official Correspondent and/or U.S. Agent Registrar Corp provides additional services such as FDA Detention Assistance, Regulatory Contact for GUDID, and FDA Gateway Transaction Partner for eMDR submissions. These services are included with your yearly Official Correspondent and/or U.S. Agent fee. For more information on these additional services please email us at medicaldevices@registrarcorp.com.

Please contact us if you have further questions. As always, we look forward to assisting you.

Sincerely,

Mirna J. Calero Manager, Medical Device Division

Registrar Corp

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24-Hour Online Live Help: www.registrarcorp.com/livehelp