

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## MBio Diagnostics, Inc.

(F003715)

Main Site: 5603 Arapahoe Ave, Suite 1, Boulder, Colorado, 80303,  
United States

has been registered by Intertek, an MDSAP recognized auditing  
organization, as conforming to the requirements of:

## ISO 13485:2016

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D), 21  
CFR 821

The management system is applicable to:

*Design, development and manufacture of instrumentation and  
disposable cartridges for biological assays for the medical device  
industry.*

**Certificate Number:**

0105845-03

**Initial Certification Date:**

01 October 2020

**Date of Certification Decision:**

19 November 2020

**Effective Date:**

19 November 2020

**Valid Until:**

30 September 2023



**Intertek**

**Calin Moldovean**

President, Business Assurance

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