

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, manufacture and servicing of instrumentation
and disposable cartridges for biological assays for the medical device
industry, and installation of related software.*

Certificate Number:

0105845-04

Initial Certification Date:

2020-10-01

Date of Certification Decision:

2021-08-12

Certification Effective Date:

2021-08-12

Certification Expiry Date:

2023-09-30



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Calin Moldovean

President, Business Assurance

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