MesaLabs

CN-170701

Customer Notification:
Bozeman Manufacturing Site: ISO Certification Change
28 Jul 2017

Dear Customer,

Mesa Laboratories, Inc. manufacturing site located at 10 Evergreen Drive, Bozeman MT, is currently certified to ISO 9001:2008 *Quality management systems - Requirements* and NF EU ISO 13485:2012 *Medical devices - Quality management systems - Requirements for regulatory purposes*.

Both standards have undergone significant revisions by the certifying bodies. Mesa has determined that ISO 9001:2015 and ISO 13485:2016 are no longer sufficiently aligned to permit compliance with both quality standards.

On or before February 2018, when site certification to ISO 13485:2016 is due, Mesa will request certification only to ISO 13485:2016. Continued certification to the ISO 13485 standard will ensure that Mesa Laboratories continues to meet both regulatory and customer requirements for a robust quality system designed specifically to meet the needs of a medical device manufacturer.

The certification of our new site located at 625 Zoot Way, Bozeman, MT, will also be to ISO 13485:2016 at the time the change is made.

We are providing this notification to you in advance and will also provide notification at the time the change is made, per our Quality or Notification Agreement.

Please contact Janis Smoke directly with any questions.

Regards,

Janis E Smoke

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