UTAK

December 21, 2018

To Whom it May Concern:

The purpose of this letter is to inform you that UTAK Laboratories, Inc. is in the process of transitioning to ISO 13485:2016 under the Medical Device Single Audit Program (MDSAP). There is an overwhelming demand of manufacturers, such as UTAK, attempting to transition to MDSAP for Health Canada compliance. UTAK Laboratories, Inc. chosen auditing organization, SAI Global, experienced difficulties accommodating the demand and as a result, UTAK's ISO 13485:2016 MDSAP Stage 2 Audit has been pushed back.

UTAK Laboratories, Inc. completed a ISO 13485:2016 MDSAP Stage 1 Audit of the Initial Certification Audit, and is working diligently with SAI Global to complete a ISO 13485:2016 MDSAP Stage 2 Audit before February 28, 2019. Successful completion of this upcoming audit will result in a ISO 13485:2016 certificate under MDSAP. While this transition is in-process, UTAK Laboratories, Inc. holds an ISO 13485:2003 Certification, which has an extended expiration date of February 28, 2019. This extension certificate supersedes the previous ISO 13485:2003 Certificate that expires December 31, 2018.

In closing, UTAK Laboratories, Inc. is committed to remain compliant with regulatory standards and bodies during the transition to ISO 13485:2016 under MDSAP. UTAK Laboratories, Inc. will provide an updated certificate as soon as it is available.

We thank you for your patience and understanding as UTAK Laboratories, Inc. transitions to ISO 13485:2016 under MDSAP.

Sincerely,

Michele White
Quality Assurance Specialist