February 18, 2021

Dear QTS Customers,

Due to continued delays at TUV-SUD, Quality Tech Services has not yet received our official ISO 13485 recertification certificate. We understand that this delay impacts the supplier control requirement that you verify QTS’s certification status.

We completed our ISO 13485:2016 recertification audit January 7th – January 10th, 2020 and received a DRAFT version of the certificate in Mid-February. After repeated requests for the updated certificate, it has been relayed that the delay is an internal TUV-SUD issue and there are no outstanding issues requiring QTS input. Multiple requests for an official letter from TUV-SUD to explain the delay have also provided no relief.

Recently, TUV-SUD completed our 1st surveillance audit February 9th – February 11th, 2021. This audit was completed with no identified findings. QTS is awaiting evidence of completion from TUV-SUD.

In the absence of the official certificate from TUV-SUD, or an official letter of status, we will continue to post the DRAFT-Certificate received in February 2020. When the official certificate arrives, we will post it to our website as quickly as possible.

We appreciate your patience in resolving this matter and look forward to our continued partnership.

If you have additional concerns or requests, please contact your customer service representative.

Kind Regards,

[Signature]

Brian D. Gaeth
Director of Quality

Attachment: DRAFT ISO 13485 Certificate
Certificate
No. Q8 066914

Holder of Certificate: Quality Tech Services, LLC
10525 Hampshire Avenue
Bloomington MN 55438
USA

Certification Mark:

Scope of Certificate: Medical Product Assembly and Packaging Services for Both Non-Sterile and Products to be Terminally Sterilized Including Coordination of Sterilization

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 72156120

Valid from: 2020-02-13
Valid until: 2023-02-12

Date, [#ISU_DT#]

Christoph Dicks
Head of Certification/Notified Body
Certificate
No. Q8 066914

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):
Quality Tech Services, LLC
10525 Hampshire Avenue, Bloomington MN 55438, USA

Quality Tech Services, LLC
4551 12th Ave E., Shakopee MN 55379, USA