

Dear QTS Customers,

Due to ongoing 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 recertification audit January 7<sup>th</sup> – January 10<sup>th</sup> 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.

A request was made for TUV-SUD to provide information regarding corrective actions to resolve the certificate delay issue. QTS has not yet received a response to this request.

In the absence of the official certificate from TUV-SUD, or an official letter of status, we will post the DRAFT-Certificate received in February. 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,



23-Sep-2020

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

**Draft From CBW 2.0 - Production System (Build - 20191217.1)**

# Certificate

No. Q8 066914

<b>Applied Standard(s):</b>	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016
<b>Facility(ies):</b>	Quality Tech Services, LLC 10525 Hampshire Avenue, Bloomington MN 55438, USA  Quality Tech Services, LLC 4551 12th Ave E., Shakopee MN 55379, USA

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