

September 22, 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 7<sup>th</sup> – January 10<sup>th</sup>, 2020 and received a DRAFT version of the certificate in Mid-February 2020. 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.

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

In September 2021, QTS received a new DRAFT certificate. In the absence of the official certificate from TUV-SUD, or an official letter of status, we will post the most recent DRAFT-Certificate. 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,



Brian D. Gaeth  
Director of Quality

Attachment: DRAFT ISO 13485 Certificate No. Q8 066914



# Certificate

No. Q8 066914

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

**Certification Mark:**



**Scope of Certificate:** **The provision of manufacturing, procedure pack manufacturing and distribution services, and Coordination of EO and irradiation services for General non-active non-implantable medical devices, Non-active implants, Devices for wound care, Non-active dental devices and accessories**

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q8\\_066914](http://www.tuvsud.com/ps-cert?q=cert:Q8_066914)

**Report No.:** 72156120

**Valid from:** 2020-02-13

**Valid until:** 2023-02-12

**Date,** [#ISU\_DT#]

Christoph Dicks  
Head of Certification/Notified Body

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# 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 S., Bloomington MN 55438, USA

The provision of manufacturing, procedure pack manufacturing and distribution services, and Coordination of EO and irradiation services for General non-active non-implantable medical devices, Non-active implants, Devices for wound care, Non-active dental devices and accessories

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

The provision of warehousing, assembly, packaging, procedure pack manufacturing and distribution services for General non-active non-implantable medical devices, Non-active implants, Devices for wound care, Non-active dental devices and accessories.

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