

Supplement to Quality System Certificate

No. SUP 003961 0002 Rev. 02

This supplement is **Q8 003961 0003 Rev. 03**
only valid in
conjunction with the
main certificate:

Certificate Holder: **Steri-Tech, Inc.**
Road 701 KM 0.7
Salinas Industrial Park
00751 Salinas
PUERTO RICO USA

Facility(ies): **Steri-Tech, Inc.**
Road 701 KM 0.7, Salinas Industrial Park, 00751 Salinas,
PUERTO RICO USA

The quality system certified as stated in the main certificate additionally fulfills the applicable requirements of

EN ISO 11135:2014 + A1:2019 Sterilization of Health-care products - Ethylene oxide - Requirements for the Development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014 + Amd. 1:2018)

Audit Report: 721004045
Dated: 2024-12-30

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

Valid from: 2025-11-07



Christoph Dicks
Head of Certification/Notified Body