



Supplement to Quality System Certificate

No. SUP 038721 0013 Rev. 03

This supplement is only valid in conjunction with the main certificate:

Q8 038721 0012 Rev. 03

Certificate Holder: Steril Verona S.r.l.

> Via S. Giuseppe 30/31 37060 Erbè (Verona)

ITALY

Facility(ies): Steril Verona S.r.l.

Via S. Giuseppe 30/31, 37060 Erbè (Verona), ITALY

Steril Verona S.r.l.

Via Fontana 2, 37054 Nogara (VR), ITALY

Steril Verona S.r.l.

Via del Lavoro 25, 37060 Trevenzuolo (VR), ITALY

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

> EN ISO 11135: 2014 "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)"

Audit Report: ITA1964654 Dated: 2022-09-02

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: 2022-11-09

Christoph Dicks

Head of Certification/Notified Body