

Supplement to Quality System Certificate

No. SUP 067057 0005 Rev. 02

This supplement is only valid in conjunction with the main certificate: **Q8 067057 0004 Rev. 03**

Certificate Holder: **ESTERILIZACIÓN, S.L.**
C/. Verneda del Congost, 12
08160 Montmeló (Barcelona)
SPAIN

Facility(ies): ESTERILIZACIÓN, S.L.
C/. Verneda del Congost, 12, 08160 Montmeló (Barcelona),
SPAIN

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 development, validation and routine control of a sterilization process for medical devices - as documented in the audit report no. ITA1453174 dated 2020-10-09

Audit Report: ITA1453174
Dated: 2020-10-09

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: 2020-11-30



Christoph Dicks
Head of Certification/Notified Body



Certificate

No. Q8 067057 0004 Rev. 03

Holder of Certificate: **ESTERILIZACIÓN, S.L.**
C/. Verneda del Congost, 12
08160 Montmeló (Barcelona)
SPAIN

Facility(ies): ESTERILIZACIÓN, S.L.
C/. Verneda del Congost, 12, 08160 Montmeló (Barcelona),
SPAIN

/

Certification Mark:



Scope of Certificate: **Ethylene Oxide Sterilization of
Medical Devices**

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

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 067057 0004 Rev. 03

Report No.: ITA1453174

Valid from: 2020-11-30

Valid until: 2023-06-11

Date, 2020-11-30



Christoph Dicks
Head of Certification/Notified Body