

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE



Product Service

Certificate

No. Q8 073061 0007 Rev. 00

Holder of Certificate: **Steril Milano S.r.l.**
Via Pompei, 6
20900 Monza (MB)
ITALY

Facility(ies):
Steril Milano S.r.l.
Via Pompei, 6, 20900 Monza (MB), ITALY

Steril Milano S.r.l.
Via Caboto, 38/40, 42046 Reggiolo (RE), ITALY

Certification Mark:



Scope of Certificate: **Sterilization with Ethylene Oxide
for medical devices.
Services of validation and periodical
monitoring of cleanrooms.**

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). See also notes overleaf.

Report No.: ITA2776082S

Valid from: 2018-10-17

Valid until: 2019-12-31

Date, 2018-10-17

Stefan Preiß



Product Service

Supplement to Quality System Certificate

No. SUP 073061 0008 Rev. 00

This supplement is **Q8 073061 0007 Rev. 00**
only valid in
conjunction with the
main certificate:

Certificate Holder: **Steril Milano S.r.l.**

Via Pompei, 6
20900 Monza (MB)
ITALY

Facility(ies):

Steril Milano S.r.l.
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Via Caboto, 38/40, 42046 Reggiolo (RE), 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: ITA2776082S

Dated: 2018-09-06

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: 2018-10-19

Stefan Preiß