ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q8 073061 0007 Rev. 01

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.: ITA1356309

Valid from: 2020-01-01
Valid until: 2022-12-31

Date, 2019-11-14

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

Product Service

Supplement to Quality System Certificate

No. SUP 073061 0008 Rev. 01

This supplement is only valid in conjunction with the main certificate: **Q8 073061 0007 Rev. 01**

Certificate Holder:

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20900 Monza (MB)
ITALY

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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: ITA1356309
Dated: 2019-09-18

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: 2020-01-01

Christoph Dicks
Head of Certification/Notified Body

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