



Product Service

Supplement to Quality System Certificate Q4N 17 01 73061 006

issued by TÜV SÜD PRODUCT SERVICE GMBH on 2017-01-10 to 2019-12-31

Steril Milano S.r.l.

Via Pompei, 6
20900 Monza (MB)
ITALIA

for the facility

Steril Milano s.r.l.

Via Pompei, 6
20900 Monza (MB)
ITALIA

Steril Milano s.r.l.

Via Caboto, 38/40
42046 Reggiolo (RG)
ITALIA

The quality system certified as stated above 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 (ISO 11135:2014)"** as documented in the audit report no. ITA277608 dated 2016-11-04

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

This supplement is valid only together with the certificate stated above.

TÜV SÜD PRODUCT SERVICE GMBH
Certification Committee for Medical Devices

Munich, 2017-01-10

Stefan Preiß

TÜV SÜD Product Service GmbH is a Notified Body (identification number 0123) according to Council Directive 93/42/ EEC concerning medical devices.

DAKKS
Deutsche
Akkreditierungsstelle
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