

Supplement to Quality System Certificate

No. SUP 016329 0035 Rev. 02

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

Q5 016329 0031 Rev. 02

Certificate Holder:



sfm medical devices GmbH

Brückenstraße 5
63607 Wächtersbach
GERMANY

Facility(ies):

sfm medical devices GmbH

Brückenstraße 5, 63607 Wächtersbach, GERMANY

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 – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (EN ISO 11135-2014)"

Audit Report:

713342892

Dated:

2024-10-01

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:

2025-05-06



Christoph Dicks
Head of Certification/Notified Body