

Supplement to Quality System Certificate

No. SUP 016329 0035 Rev. 01

This supplement is only valid in conjunction with the main certificate: **Q5 016329 0031 Rev. 01**

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: 713221355

Dated: 2022-02-02

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: 2022-08-01



Christoph Dicks
Head of Certification/Notified Body