



Certificate

No. Q8 111131 0001 Rev. 00

Holder of Certificate: **Grünewald GmbH**

Sophie-Opel-Str. 16
64625 Bensheim
GERMANY

Facility(ies):

Grünewald GmbH
Sophie-Opel-Str. 16, 64625 Bensheim, GERMANY

see Scope of Certificate

Certification Mark:



Scope of Certificate:

Provision of regulatory Compliance Services for the evaluation of Risk Management of non-active implants in trauma care, for the evaluation of Usability and draw up of Technical documentation of active medical devices in the field of anesthesia and intensive care, for the Qualification of equipment and Validation of production processes of in-vitro diagnostic products and their reagents

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:Q8 111131 0001 Rev. 00

Report No.: 713203443

Valid from: 2021-12-08

Valid until: 2024-12-07

Date, 2021-12-08



Christoph Dicks
Head of Certification/Notified Body