



Certificate

No. Q5 140091 0001 Rev. 00

Holder of Certificate: **OrphaCare GmbH**
Leopold-Ungar-Platz 2/1/132
1190 Wien
AUSTRIA

Certification Mark:



Scope of Certificate: **Development and manufacturing of medical software for Therapies or support for therapies using portable external and subcutaneously implantable infusion pumps.**

The provision of marketing, distribution and servicing services for medical devices.

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 140091 0001 Rev. 00

Report No.: 713418203

Valid from: 2026-09-29

Valid until: 2028-03-20

Date, 2026-09-29

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **OrphaCare GmbH**
Leopold-Ungar-Platz 2/1/132, 1190 Wien, AUSTRIA

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