



Certificate

No. Q5 035970 0015 Rev. 01

Holder of Certificate: **Debiotech S.A.**
Avenue de Sévelin, 28
1004 Lausanne
SWITZERLAND

Certification Mark:



Scope of Certificate: **Design and development, production, and distribution of:**

- External infusion pumps
- Insulin delivery systems
- Infusion sets
- Dialysis systems
- Contrast media injection systems
- Micro needles and non-active injection devices
- Drug delivery systems
- Point-of-care in vitro diagnostic systems
- Remote and wireless communication systems for medical devices

Design and development of:

- Implantable infusion pumps
- Drug eluting stents and implantable drug eluting devices
- Coatings for implantable medical devices
- Hydrocephalic valves

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). See also notes overleaf.

Report No.: 713160492

Valid from: 2019-10-01

Valid until: 2022-09-30

Date, 2019-09-25

Stefan Preiß
Head of Certification/Notified Body

Certificate

No. Q5 035970 0015 Rev. 01

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Debiotech S.A.
Avenue de Sévelin, 28, 1004 Lausanne, SWITZERLAND

./.

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT