CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Certificate

No. Q5 115717 0001 Rev. 02

Holder of Certificate: **hemotune AG**
Wagistrasse 27
8952 Schlieren
SWITZERLAND

Certification Mark:



Scope of Certificate: **Design and Development, Production, Distribution, and Service of Sterile and Non-Sterile Medical Devices for Blood Purification and Design and Development, Production, Distribution of Sterile and Non-Sterile Coated Colloidal Nanoparticles with Specific Binding Sites for Blood Purification.**

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 115717 0001 Rev. 02

Report No.: 713386971

Valid from: 2026-07-21
Valid until: 2029-07-20

Date, 2026-06-26

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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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):

hemotune AG
Wagistrasse 27, 8952 Schlieren, SWITZERLAND

See Scope of Certificate

hemotune AG
Wagistrasse 6, 8952 Schlieren, SWITZERLAND

Production of Non-Sterile and storage of sterile and non-sterile Medical Devices for Blood Purification

hemotune AG c/o ETH Zürich
Vladimir-Prelog-Weg 1, 8093 Zürich, SWITZERLAND

Production of Non-Sterile Nanoparticles for Blood Purification

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