



Product Service

# Certificate

No. Q5 046012 0013 Rev. 03

**Holder of Certificate:** **HEMOTEQ AG**  
Adenauerstrasse 15  
52146 Würselen  
GERMANY

**Certification Mark:**



**Scope of Certificate:** **Design and development, manufacturing and distribution of medical device combination products including Drug-coated Balloon catheters for cardiovascular and peripheral vascular interventional procedures. Provision of Design and development and manufacturing services of coatings and coating substances including drug-coatings, for implants and medical disposables.**

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\\_046012\\_0013\\_Rev.03](http://www.tuvsud.com/ps-cert?q=cert:Q5_046012_0013_Rev.03)

**Report No.:** 713342052

**Valid from:** 2024-11-19  
**Valid until:** 2027-11-12

**Date,** 2024-11-19

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):** **HEMOTEQ AG**  
Adenauerstrasse 15, 52146 Würselen, GERMANY

see scope of certificate

**HEMOTEQ AG**  
William-Prym-Straße 26, 52477 Alsdorf, GERMANY

Provision of Design and development and manufacturing services  
of coatings and coating substances including drug-coatings, for  
implants and medical disposables.

**Parameters:** ./.