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

Product Service

Certificate

No. Q5 102681 0001 Rev. 00

Holder of Certificate: **anteris medical GmbH**
Münchner Str. 47e
83607 Holzkirchen
GERMANY

Facility(ies):
anteris medical GmbH
Münchner Str. 47e, 83607 Holzkirchen, GERMANY

anteris medical GmbH
Bergfeldstr. 9, 83607 Holzkirchen, GERMANY

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development of Medical Devices, including IVD Devices and Combination Products, as well as Support of Manufacturers in the area of Design and Development, Quality Management and Regulatory Compilance.**

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). See also notes overleaf.

Report No.: 713150575

Valid from: 2019-08-28
Valid until: 2022-08-27

Date, 2019-08-28

Stefan Preiß
Head of Certification/Notified Body

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17