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

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

Product Service

Certificate

No. Q5 096981 0002 Rev. 02

Holder of Certificate: **Ventana Medical Systems, Inc.**
1910 East Innovation Park Drive
Tucson AZ 85755
USA

Certification Mark:

Scope of Certificate: **Design, development, and manufacture of in-vitro diagnostic instruments, software and reagents used in clinical research, cytology and histology to aid in the identification and/or differentiation of tumor markers and infectious disease agents in tissue**

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 096981 0002 Rev. 02

Report No.: 713318558/ 713318558_CN

Valid from: 2024-08-20
Valid until: 2027-08-19

Date, 2024-07-05

Christoph Dicks
Head of Certification/Notified Body

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

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No. Q5 096981 0002 Rev. 02

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):

Ventana Medical Systems, Inc.
1910 East Innovation Park Drive, Tucson AZ 85755, USA

Design and development of in-vitro diagnostic instruments, software and reagents, and manufacture of in-vitro diagnostic reagents used in clinical research, cytology and histology to aid in the identification and/or differentiation of tumor markers and infectious disease agents in tissue

Ventana Medical Systems, Inc.
9831 West Tangerine Road, Marana AZ 85653, USA

Receiving, inspection and storage of raw materials, and manufacture of in-vitro diagnostic instruments used in clinical research, cytology and histology to aid in the identification and/or differentiation of tumor markers and infectious disease agents in tissue

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