



Certificate

No. Q5 096981 0002 Rev. 00

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 and certification regulation of 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. 00

Report No.: 713207013

Valid from: 2021-08-20
Valid until: 2024-08-19

Date, 2021-08-20



Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 096981 0002 Rev. 00

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):

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

Design, development, and manufacture of in-vitro diagnostic instruments 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

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

Manufacture (packaging and warehousing) 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.
2801 Scott Boulevard, Santa Clara CA 95050, USA

Design and development of in-vitro diagnostic software used in digital pathology

Parameters: ./.