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

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 096981 0003 Rev. 00

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

SRN Manufacturer: Not available at issuance date of this certificate

Authorized Representative:
Roche Diagnostics GmbH
Sandhofer Strasse 116, 68305 Mannheim, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 096981 0003 Rev. 00

Report No.: 713207013

Valid from: 2021-11-04

Valid until: 2026-11-03

Issue date: 2021-11-04

Christoph Dicks
Head of Certification/Notified Body

REPUBLICA MOLDOVA, mun. CHIŞINĂU IDNO 1003600060828 I.M. «BECOR» S.R.L. PENTRU CONTRACTE SOCIETATEA CU RĂSPUNDERE LIMITATĂ

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Digitally signed by Lazari Cristina
Date: 2023.06.28 13:50:57 EEST
Reason: MoldSign Signature
Location: Moldova

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No. V12 096981 0003 Rev. 00

Classification:	B
Device Group:	W010307 - HISTOLOGY/CYTOLOGY REAGENTS
Intended Purpose:	IVR 0506 - Other devices intended to be used to determine markers of infections/immune status

Classification:	B
Device Group:	W010307 - HISTOLOGY/CYTOLOGY REAGENTS
Intended Purpose:	IVR 0701 - Devices which are controls without a quantitative assigned value

Classification:	C
Device Group:	W010307 - HISTOLOGY/CYTOLOGY REAGENTS
IVP Code:	IVP 3010 - In vitro diagnostic devices which require knowledge regarding microscopy
Intended Purpose:	IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer

Classification:	C
Device Group:	W010307 - HISTOLOGY/CYTOLOGY REAGENTS
IVP Code:	IVP 3010 - In vitro diagnostic devices which require knowledge regarding microscopy
Intended Purpose:	IVR 0302 - Other devices intended to be used for markers of cancer and non-malignant tumours

The validity of this certificate depends on conditions and/or is limited to the following: -none-

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