EU Declaration of Conformity

In accordance with EU Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

Manufacturer:	**Ventana Medical Systems Inc.** **1910 E Innovation Park Drive** **Tucson, AZ 85755, USA**
Single Registration Number (SRN) Manufacturer:	**US-MF-000016993**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**DE-AR-000006262**

This declaration is issued under the sole responsibility of Ventana Medical Systems Inc.

Product Information

Part Number:	Product Name:	Basic UDI-DI:
05278384001 (alternative P/N: 790-4286)	CONFIRM anti-Ki-67 (30-9) Rabbit Monoclonal Primary Antibody	761333601192AG

Intended Purpose:	CONFIRM anti-Ki-67 (30-9) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of Ki-67 protein by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument.
Risk Class:	Class C
Common Specifications:	Not applicable as no Common Specifications exist for the concerned device.
Name, Address and Identification number of the Notified Body:	TÜV SÜD Product Service GmbH (No. 0123) Ridlerstraße 65 80339 MÜNCHEN Germany

Conformity Assessment was established through the procedure described in Annex IX of EU Regulation 2017/746, including an assessment of the Technical Documentation as described in Annex IX, Chapter II. This declaration is supported by the following certificate(s):

EU Quality Management System Certificate: V12 096981 0003

Conformity of the product with EU Regulation 2017/746 and other applicable EU legislation has been established.

On behalf of Ventana Medical Systems Inc.

Place: Tucson, AZ 85755, USA

Date: 22-Jun-2022

Jeff Boone

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 21-Jun-2022

Ben Curson

Benjamin Curson

Site Head of Regulatory Affairs Function

EU Declaration of Conformity

In accordance with EU Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

Manufacturer:	**Ventana Medical Systems Inc.** **1910 E Innovation Park Drive** **Tucson, AZ 85755, USA**
Single Registration Number (SRN) Manufacturer:	**US-MF-000016993**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**DE-AR-000006262**

This declaration is issued under the sole responsibility of Ventana Medical Systems Inc.

Product Information

Part Number:	Product Name:	Basic UDI-DI:
06695248001 (alternative P/N: 805-4713) 06695256001 (alternative P/N: 825-4713)	CINtec® p16 Histology	761333601839BF

Intended Purpose:	CINtec p16 Histology is an immuno-histochemistry assay for the qualitative detection of the p16INK4a protein on formalin-fixed, paraffin-embedded tissue sections prepared from cervical biopsies. It is indicated to be used in conjunction with H&E stained slides prepared from the same cervical tissue specimen as an aid to increase diagnostic accuracy and inter-observer agreement in the diagnosis of high grade cervical intraepithelial neoplasia.
Risk Class:	Class C
Common Specifications:	Not applicable as no Common Specifications exist for the concerned device.
Name, Address and Identification number of the Notified Body:	TÜV SÜD Product Service GmbH (No. 0123) Ridlerstraße 65 80339 MÜNCHEN Germany

Conformity Assessment was established through the procedure described in Annex IX of EU Regulation 2017/746, including an assessment of the Technical Documentation as described in Annex IX, Chapter II. This declaration is supported by the following certificate(s):

EU Quality Management System Certificate: V12 096981 0003

Conformity of the product with EU Regulation 2017/746 and other applicable EU legislation has been established.

On behalf of Ventana Medical Systems Inc.

Place: Tucson, AZ 85755, USA

Date: 27 November 2022

DocuSigned by:
Jeff Boone
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Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 22 November 2022

DocuSigned by:
Benjamin Curson
6E68FEBA2C01421...

Benjamin Curson

Site Head of Regulatory Affairs Function

EU Declaration of Conformity

In accordance with EU Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

Manufacturer:	**Ventana Medical Systems Inc.** **1910 E Innovation Park Drive** **Tucson, AZ 85755, USA**
Single Registration Number (SRN) Manufacturer:	**US-MF-000016993**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**DE-AR-000006262**

This declaration is issued under the sole responsibility of Ventana Medical Systems Inc.

Product Information

Part Number:	Product Name:	Basic UDI-DI:
05277990001 (alternative P/N: 790-2223) 50 tests	CONFIRM anti-Progesterone Receptor (PR) (1E2) Rabbit Monoclonal Primary Antibody	761333601236AB
05278392001 (alternative P/N: 790-4296) 250 tests		

Intended Purpose: CONFIRM anti-Progesterone Receptor (PR) (1E2) Rabbit Monoclonal (IgG) Primary Antibody is intended for laboratory use in the qualitative detection of progesterone receptor (PR) antigen in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer with VENTANA detection kits and ancillary reagents. CONFIRM anti-PR (1E2) antibody is directed against an epitope present on human progesterone receptor protein located in the nucleus of PR positive normal and neoplastic cells. CONFIRM anti-PR (1E2) antibody is indicated as an aid in the management, prognosis, and prediction of therapy outcome of breast carcinoma. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. Prescription use only. This antibody is intended for in vitro diagnostic (IVD) use.

Risk Class: Class C

Common Specifications: Not applicable as no Common Specifications exist for the concerned devices.

Name, Address and Identification number of the Notified Body:	TÜV SÜD Product Service GmbH (No. 0123) Ridlerstraße 65 80339 MÜNCHEN Germany

Conformity Assessment was established through the procedure described in Annex IX of EU Regulation 2017/746, including an assessment of the Technical Documentation as described in Annex IX, Chapter II. This declaration is supported by the following certificate(s):

EU Quality Management System Certificate: V12 096981

Conformity of the product with EU Regulation 2017/746 and other applicable EU legislation has been established.

On behalf of Ventana Medical Systems Inc.

Place: Tucson, AZ 85755, USA

Date: 26-Jan-2022

DocuSigned by:
Jeff Boone
D9C56B8025BB4D8...

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 31-Jan-2022

DocuSigned by:
Ben Curson
6E68FEBA2C01421...

Benjamin Curson

Site Head of Regulatory Affairs Function

EU Declaration of Conformity

In accordance with EU Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

Manufacturer:	**Ventana Medical Systems Inc.** **1910 E Innovation Park Drive** **Tucson, AZ 85755, USA**
Single Registration Number (SRN) Manufacturer:	**US-MF-000016993**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**DE-AR-000006262**

This declaration is issued under the sole responsibility of Ventana Medical Systems Inc.

Product Information

Part Number:	Product Name:	Basic UDI-DI:
05266688001 (alternative P/N: 760-2018)	Protease 1	761333601904AZ

Intended Purpose: Protease 1 is an endopeptidase (alkaline protease) of the serine protease family and cleaves proteins in the tissue section, allowing primary antibodies to recognize and bind epitope(s). The reagent is intended for enzymatic digestion of sections of routine formalin-fixed, paraffin-embedded tissue on a Benchmark IHC/ISH instrument.
This reagent is intended for in vitro diagnostic (IVD) use.

Risk Class: Class A

Common Specifications: Not applicable as no Common Specifications exist for the concerned device.

Conformity of the product with EU Regulation 2017/746 and other applicable EU legislation has been established.

On behalf of Ventana Medical Systems Inc.

Place: Tucson, AZ 85755, USA

Date: 29-Mar-2022

Jeff Boone

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 28-Mar-2022

Ben Curson

Benjamin Curson

Site Head of Regulatory Affairs Function

EU Declaration of Conformity

In accordance with EU Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

Manufacturer:	**Ventana Medical Systems Inc.** **1910 E Innovation Park Drive** **Tucson, AZ 85755, USA**
Single Registration Number (SRN) Manufacturer:	**US-MF-000016993**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**DE-AR-000006262**

This declaration is issued under the sole responsibility of Ventana Medical Systems Inc.

Product Information

Part Number:	Product Name:	Basic UDI-DI:
05279771001 (alternative P/N: 950-102)	EZ Prep Concentrate (10X)	761333601901AT

Intended Purpose: Ventana Medical Systems' (Ventana) EZ Prep Concentrate (10X) solution (EZ Prep) is used for paraffin removal from tissue samples during immunohistochemistry and in situ hybridization reactions, and to dilute 2X SSC during stringency washes during in situ hybridization reactions carried out on Ventana automated slide stainers.

This product is designed for use on BenchMark Series automated slide stainers.

This product is intended for in vitro diagnostic (IVD) use.

Risk Class: Class A

Common Specifications: Not applicable as no Common Specifications exist for the concerned device.

Conformity of the product with EU Regulation 2017/746 and other applicable EU legislation has been established.

On behalf of Ventana Medical Systems Inc.

Place: Tucson, AZ 85755, USA

Date: 29-Mar-2022

Jeff Boone

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 28-Mar-2022

Ben Curson

Benjamin Curson

Site Head of Regulatory Affairs Function

EU Declaration of Conformity

In accordance with EU Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

Manufacturer:	**Ventana Medical Systems Inc.** **1910 E Innovation Park Drive** **Tucson, AZ 85755, USA**
Single Registration Number (SRN) Manufacturer:	**US-MF-000016993**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**DE-AR-000006262**

This declaration is issued under the sole responsibility of Ventana Medical Systems Inc.

Product Information

Part Number:	Product Name:	Basic UDI-DI:
05264839001 (alternative P/N: 650-010)	LCS (Predilute)	7613336012209U

Intended Purpose: LCS (Predilute) is a prediluted coverslip solution intended for laboratory use as a barrier between the aqueous reagents and the air. This barrier prevents evaporation, thereby providing a stable aqueous environment for the immunohistochemistry, immunocytochemistry, or in situ hybridization reactions on BenchMark GX and BenchMark XT instruments. This reagent is intended for in vitro diagnostic use.

Risk Class: Class A

Common Specifications: Not applicable as no Common Specifications exist for the concerned device.

Conformity of the product with EU Regulation 2017/746 and other applicable EU legislation has been established.

On behalf of Ventana Medical Systems Inc.

Place: Tucson, AZ 85755, USA

Date: 22-Feb-2022

DocuSigned by:
Jeff Boone

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 01-Mar-2022

Ben Curson

Benjamin Curson

Site Head of Regulatory Affairs Function

EU Declaration of Conformity

In accordance with EU Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

Manufacturer:	**Ventana Medical Systems Inc.** **1910 E Innovation Park Drive** **Tucson, AZ 85755, USA**
Single Registration Number (SRN) Manufacturer:	**US-MF-000016993**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**DE-AR-000006262**

This declaration is issued under the sole responsibility of Ventana Medical Systems Inc.

Product Information

Part Number:	Product Name:	Basic UDI-DI:
05446724001 (alternative P/N: 780-003)	ultraView Silver Wash II	761333601900AR

Intended Purpose:	ultraView Silver Wash II solution is intended for laboratory use to provide an appropriate aqueous environment prior to silver detection chemistry steps on a BenchMark IHC/ISH instrument. This product is intended for *in vitro* diagnostic (IVD) use.
Risk Class:	Class A
Common Specifications:	Not applicable as no Common Specifications exist for the concerned device.

Conformity of the product with EU Regulation 2017/746 and other applicable EU legislation has been established.

On behalf of Ventana Medical Systems Inc.

Place: Tucson, AZ 85755, USA

Date: 22-Feb-2022

DocuSigned by:
Jeff Boone

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 01-Mar-2022

Ben Curson

Benjamin Curson

Site Head of Regulatory Affairs Function

VENTANA®

a member of the Roche Group

Ventana Medical Systems, Inc.
1910 E. Innovation Park Drive
Tucson, Arizona 85755
Phone: (520) 887-2155
Toll Free: (800)-227-2155
www.ventana.com

Declaration of Conformity to 98/79/EC

Manufacturer:	Ventana Medical Systems, Inc. 1910 E. Innovation Park Drive Tucson, AZ USA 85755
European Authorized Representative:	ROCHE DIAGNOSTICS GmbH Sandhofer Strasse 116 D-68305 Mannheim Germany
Manufacturing Site:	Tucson, AZ USA

		Ventana REF	Roche
Product name/ Catalogue No.	ultraView Universal Alkaline Phosphatase Red Detection Kit	760-501	05269814001
Technical Data File:	D018734		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

Ventana Medical Systems, Inc. declares that the product(s) listed is/are in conformity with the essential requirements of Annex I of Council Directive 98/79/EC. All supporting documentation is retained under the premise of the Manufacturer.

Ventana Medical Systems, Inc. maintains a quality system based on EN ISO 13485:2012 / EN ISO 13485:2012 + AC:2012 as certified by TÜV Rheinland LGA Products GmbH (Notified Body No. 0197).

Place of Issue: Tucson, AZ USA 85755

Name of Authorized Signatory: Deepshikha Bhandari
Vice President, Regulatory Affairs

Signature: _____ Date: 11-May-2016

Roxane Bonner for
Deepshikha Bhandari

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Phone: (520) 887-2155
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Declaration of Conformity to 98/79/EC

Manufacturer:	Ventana Medical Systems, Inc. 1910 E. Innovation Park Drive Tucson, AZ USA 85755
European Authorized Representative:	ROCHE DIAGNOSTICS GmbH Sandhofer Strasse 116 D-68305 Mannheim Germany
Manufacturing Site:	Tucson, AZ USA

		Ventana REF	Roche
Product name/ Catalogue No.	Hematoxylin	760-2021	05266726001

Technical Data File:	TDF-0043
Classification:	General IVD
Conformity Assessment:	98/79/EC Annex III

Ventana Medical Systems, Inc. declares that the product(s) listed is/are in conformity with the essential requirements of Annex I of Council Directive 98/79/EC. All supporting documentation is retained under the premise of the Manufacturer.

Ventana Medical Systems, Inc. maintains a quality system based on EN ISO 13485:2012 / EN ISO 13485:2012 + AC:2012 as certified by TÜV Rheinland LGA Products GmbH (Notified Body No. 0197).

Place of Issue:	Tucson, AZ USA 85755
Name of Authorized Signatory:	Troy Quander Vice President, Regulatory Affairs

Signature: Troy Quander Date: 5-March-2015

VENTANA®

a member of the Roche Group

Ventana Medical Systems, Inc.
1910 E. Innovation Park Drive
Tucson, Arizona 85755
Phone: (520) 887-2155
Toll Free: (800)-227-2155
www.ventana.com

Declaration of Conformity to 98/79/EC

Manufacturer:	Ventana Medical Systems, Inc. 1910 E. Innovation Park Drive Tucson, AZ USA 85755
European Authorized Representative:	ROCHE DIAGNOSTICS GmbH Sandhofer Strasse 116 D-68305 Mannheim Germany
Manufacturing Site:	Tucson, AZ USA

		Ventana REF	Roche
Product name/ Catalogue No.	Bluing Reagent	760-2037	05266769001
Technical Data File:	TDF 0046		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

Ventana Medical Systems, Inc. declares that the product(s) listed is/are in conformity with the essential requirements of Annex I of Council Directive 98/79/EC. All supporting documentation is retained under the premise of the Manufacturer.

Ventana Medical Systems, Inc. maintains a quality system based on EN ISO 13485:2012 / EN ISO 13485:2012 + AC:2012 as certified by TÜV Rheinland LGA Products GmbH (Notified Body No. 0197).

Place of Issue: Tucson, AZ USA 85755

Name of Authorized Signatory: Troy Quander
Vice President, Regulatory Affairs

Signature: Troy Quander Date: 16 April 2015

EU Declaration of Conformity

In accordance with EU Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

Manufacturer:	**Ventana Medical Systems Inc.** **1910 E Innovation Park Drive** **Tucson, AZ 85755, USA**
Single Registration Number (SRN) Manufacturer:	**US-MF-000016993**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**DE-AR-000006262**

This declaration is issued under the sole responsibility of Ventana Medical Systems Inc.

Product Information

Part Number:	Product Name:	Basic UDI-DI:
05277965001 (alternative P/N: 790-2208)	Hematoxylin II	761333601224A4

Intended Purpose: Hematoxylin II is a modified Mayer's hematoxylin intended for laboratory use in staining cellular nuclei on slides containing cells from frozen tissue, or formalin fixed, paraffin-embedded tissue on a BenchMark IHC/ISH instrument. This reagent is intended as a counterstain to immunohistochemistry, and in situ hybridization applications. This reagent is intended for in vitro diagnostic use.

Risk Class: Class A

Common Specifications: Not applicable as no Common Specifications exist for the concerned device.

Conformity of the product with EU Regulation 2017/746 and other applicable EU legislation has been established.

On behalf of Ventana Medical Systems Inc.

Place: Tucson, AZ 85755, USA

Date: 22-Feb-2022

DocuSigned by:
Jeff Boone
D9C56B8025BB4D8...

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 01-Mar-2022

Ben Curson

Benjamin Curson

Site Head of Regulatory Affairs Function

Declaration of Conformity

as per Annex III of Directive 98/79/EC of the European Parliaments and Council of 27 October 1998

Manufacturer:

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

Roche Diagnostics GmbH declares that the product/the product line

Product name:	**VENTANA PD-L1 (SP263) Assay**
Roche Id.-No.:	**07419821001**
Ventana Id.-No.:	**741-4905**

to which this declaration relates fulfils the requirements of Directive 98/79/EC of the European Parliament and Council of 27 October 1998 on in-vitro diagnostic medical devices (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market).

Mannheim, 28 April 2022

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Ralf Zielenski
A7F0BA9FE91A46A...

Ralf Zielenski
Head Q&R Compliance, PRRC RDG
Centralised and Point of Care Solutions

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
FC5EDEC1054B44C...

Dr. Stefan Scheib
Network Lead Core Lab, Global Regulatory Affairs
Centralised and Point of Care Solutions

Kontaktadresse/*Contact address*: Roche Diagnostics GmbH
Abt./*Dept.* Global Regulatory Affairs
Sandhofer Strasse 116
68305 Mannheim
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Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker