



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) **US-MF-000016993**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany**

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
08035130001 (alternative P/N: 790-6011)	anti-p504s (SP116) Rabbit Monoclonal Primary Antibody	761333601235A9

Intended Purpose: Anti-p504s (SP116) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of α -methylacyl-CoA racemase (AMACR, also known as p504s) 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

18-Jul-2022

Date:

Jeff Boone

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

19-Jul-2022

Date:

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) **US-MF-000016993**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany**

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
05929903001 (alternative P/N: 790-4451)	CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody	761333601857BH

Intended Purpose: CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD5 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) **US-MF-000016993**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany**

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
06537847001 (alternative P/N: 790-4558)	anti-CD7 (SP94) Rabbit Monoclonal Primary Antibody	761333601858BK

Intended Purpose: Anti-CD7 (SP94) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD7 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:

DocuSigned by:

Jeff Boone

19C56B8025BB4D8...

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date:

DocuSigned by:

Benjamin Curson

61F6814FBAA2C01421

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) **US-MF-000016993**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany**

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
09780041001 (alternative P/N 790-7176)	anti-CD8 (SP239) Rabbit Monoclonal Primary Antibody	761333602693BJ

Intended Purpose: Anti-CD8 (SP239) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD8 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:

DocuSigned by:



D9C56RA025BR4D8

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date:

DocuSigned by:



6F68FFBA2C01421

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) **US-MF-000016993**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany**

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
07007841001 (alternative P/N: 790-4858)	anti-CD30 (Ber-H2) Mouse Monoclonal Primary Antibody	761333601206A2

Intended Purpose: The anti-CD30 (Ber-H2) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of the CD30 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

18-Jul-2022

Date:

Jeff Boone

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

19-Jul-2022

Date:

Ben Curson

Benjamin Curson

Site Head of Regulatory Affairs Function



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	Roche
	[REF]	
Product name/	Anti-CD44 (SP37) Rabbit	790-4537
Catalogue No.	Monoclonal Primary Antibody	06364985001
Technical Data File:	TDF-0426	
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: Fatima Pereira
Director, Regulatory Affairs

Signature: 

Date: 06 - May - 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) **US-MF-000016993**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH**
Sandhofer Strasse 116
68305 Mannheim
Germany

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
05278252001 (alternative P/N: 790-2931)	CONFIRM anti-CD68 (KP-1) Primary Antibody	761333601225A6

Intended Purpose: CONFIRM anti-CD68 (KP-1) Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD68 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:

DocuSigned by:

Jeff Boone
Jeff Boone

00C56B80251B4D8...

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date:

DocuSigned by:

Benjamin Curson
Benjamin Curson

003FEB42C01421...

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) **US-MF-000016993**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH**
Sandhofer Strasse 116
68305 Mannheim
Germany

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
05640296001 (alternative P/N: 790-4432)	Confirm anti-CD79a (SP18) Rabbit Monoclonal Primary Antibody	7613336012149Z

Intended Purpose: CONFIRM anti-CD79a (SP18) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD79a 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:

DocuSigned by:

Jeff Boone

DOC-56B8025B5B4D8...

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date:

DocuSigned by:

Benjamin Curson

61E69CFBA2C00421

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) **US-MF-000016993**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH**
Sandhofer Strasse 116
68305 Mannheim
Germany

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
05913594001 (alternative P/N: 790-4452)	Confirm anti-CD99 (O13) Mouse Monoclonal Primary Antibody	761333601872BD

Intended Purpose: CONFIRM anti-CD99 (O13) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD99 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:

DocuSigned by:

Jeff Boone

09C5688025BB4D8...

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date:

DocuSigned by:

Benjamin Curson

6F69FF8A2001421

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) **US-MF-000016993**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany**

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
08763909001 (alternative P/N: 790-7061)	anti-CD117 (EP10) Rabbit Monoclonal Primary Antibody	761333601196AQ

Intended Purpose: Anti-CD117 (EP10) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD117 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:

DocuSigned by:

Jeff Boone

1D9C56B80258B4D8...

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date:

DocuSigned by:

Benjamin Curson

DE623FEBAA2C01721...

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) **US-MF-000016993**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany**

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
05267056001 (alternative P/N: 760-2519)	Anti-Chromogranin A (LK2H10) Primary Antibody	761333601709AZ

Intended Purpose: Anti-Chromogranin A (LK2H10) Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of chromogranin A 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:

DocuSigned by:

Jeff Boone

59c56b80256b4d8...

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date:

DocuSigned by:

Benjamin Curson

61c681ef0a2c01421

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) **US-MF-000016993**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany**

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
05267145001 (alternative P/N: 760-2595)	Anti-Pan Keratin (AE1/AE3/PCK26)	761333601183AF
05266840001 (alternative P/N: 760-2135)	Primary Antibody	

Intended Purpose: Anti-Pan Keratin (AE1/AE3/PCK26) Primary Antibody is an antibody cocktail intended for laboratory use in the qualitative immunohistochemical detection of most acidic cytokeratins and all basic cytokeratins 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

22-Jun-2022

Date:

Jeff Boone

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

21-Jun-2022

Date:

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) **US-MF-000016993**
 Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH**
Sandhofer Strasse 116
68305 Mannheim
Germany

Single Registration Number (SRN) **DE-AR-000006262**
 Authorized Representative:

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
06478425001 (alternative P/N: 790-4555)	anti-Cytokeratin (CAM 5.2) Mouse Monoclonal Primary Antibody	761333601182AD

Intended Purpose: Anti-Cytokeratin (CAM 5.2) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of cytokeratin 7 (CK7) and cytokeratin 8 (CK8) by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument.

This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

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 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

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:

A handwritten signature in black ink, appearing to read "Jeff Boone".

DOC5688025BB4D8...

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 01-Mar-2022

A handwritten signature in black ink, appearing to read "Ben Curson".

Benjamin Curson

Site Head of Regulatory Affairs Function



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	Roche
	REF	
Product name/	anti-Cytokeratin 5/6	790-4554
Catalogue No.	(D5/16B4) Mouse Monoclonal Primary Antibody	06478441001
Technical Data File:	TDF-0433	
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:

Date: 10 - March - 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) **US-MF-000016993**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany**

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
05986818001 (alternative P/N: 790-4462)	CONFIRM anti-Cytokeratin 7 (SP52) Rabbit Monoclonal Primary Antibody	761333601187AP

Intended Purpose: CONFIRM anti-Cytokeratin 7 (SP52) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of cytokeratin 7 (CK7) 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

22-Jun-2022

Date:

A handwritten signature in black ink that reads "Jeff Boone".

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

21-Jun-2022

Date:

A handwritten signature in black ink that reads "Ben Curson".

Benjamin Curson

Site Head of Regulatory Affairs Function