

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:
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

Place: Tucson, AZ 85755, USA

Date: 22-Feb-2022

Date: 01-Mar-2022

DocuSigned by:

Jeff Boone
 Jeff Boone

Site Head of Quality Function

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:
05424542001 (alternative P/N: 950-223)	ULTRA Cell Conditioning Solution (ULTRA CC2)	761333601914B4

Intended Purpose: ULTRA Cell Conditioning Solution (ULTRA CC2) is a prediluted solution intended for laboratory use as a pretreatment step in the processing of formalin-fixed, paraffin-embedded tissue samples during immunohistochemistry and in situ hybridization applications on the BenchMark ULTRA 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

Place: Tucson, AZ 85755, USA

Date: 22-Feb-2022

Date: 01-Mar-2022

DocuSigned by:


 Jeff Boone

Site Head of Quality Function



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:
05278511001 (alternative P/N: 800-092)	VENTANA ISH iVIEWBlue Detection Kit	761333601834B5

Intended Purpose: VENTANA ISH iVIEW Blue Detection Kit is an indirect biotin streptavidin system for the detection of fluorescein-labeled probes. The kit is intended to identify targets by in situ hybridization in sections of formalin-fixed, paraffin-embedded tissue that are stained 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

Place: Tucson, AZ 85755, USA

Date: 29-Mar-2022

Date: 28-Mar-2022

Jeff Boone

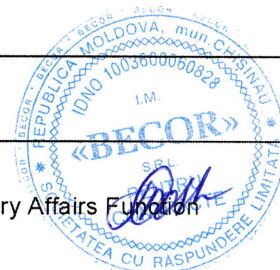
Ben Curson

Jeff Boone

Benjamin Curson

Site Head of Quality Function

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:
05272017001 (alternative P/N: 780-2218)	Red Counterstain II	761333601907B7

Intended Purpose: Red Counterstain II is intended to aid microscopic bright field observation for in situ hybridization applications. Red Counterstain II is for use with 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) **US-MF-000016993**
 Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH**
Sandhofer Strasse 116
D-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.

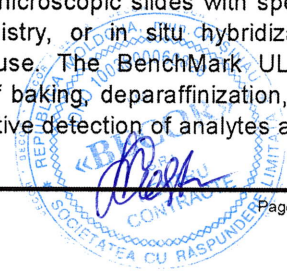
Product Information

Part Number:	Product Name:	Basic UDI-DI:
05342716001 (alternative P/N 750-600)	BenchMark ULTRA Instrument	761333602109AA

Accessories		
Part Number	Product Name	Basic UDI-DI
05424585001 (alternative P/N 1697400)	Kit, accessory 1, ULTRA	761333602109AA
05424577001 (alternative P/N 2505700)	Kit, accessory 2, ULTRA	
05250986001 (alternative P/N 1650800)	Assembly, waste container and cart	

Intended Purpose:

The BenchMark ULTRA instrument is intended to automatically stain histological or cytological specimens on microscopic slides with specific immunohistochemistry, immunocytochemistry, or *in situ* hybridization reagents for *in vitro* diagnostic (IVD) use. The BenchMark ULTRA instrument fully automates the process of baking, deparaffinization, and staining of the qualitative or semi quantitative detection of analytes as an





aid in diagnosis by pathologists. The system is intended for use in the anatomic pathology (AP) laboratory environment by trained laboratory personnel who are knowledgeable in histology processes and have basic computer operation skills

Risk Class and Classification Rule: Class A, as per EU Regulation 2017/746, Annex VIII, Rule 5

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

Conformity of the product with EU Regulation 2017/746 and the following EU legislation, which also require an EU Declaration of Conformity, and other applicable EU legislation, has been established.

- Complies with the requirements of Directive 2011/65/EU including amendment of Annex II 2015/863/EU of 31st March 2015 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

On behalf of Ventana Medical Systems Inc.

Place: Tucson, AZ 85755, USA

Place: Tucson, AZ 85755, USA

Date: 09 November 2022

Date: 10 November 2022

DocuSigned by:
Jeff Boone

DocuSigned by:
Benjamin Curson

Jeff Boone

Benjamin Curson

Site Head of Quality Function

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
D-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:
09576797001	BenchMark ULTRA PLUS Instrument	761333602634B2

Install Components/Accessories		
Part Number	Product Name	Basic UDI-DI
08706905001	BenchMark ULTRA PLUS Accessory Kit	761333602634B2
08706956001	BenchMark ULTRA PLUS Bottle ship kit	
08270635001	BenchMark ULTRA PLUS Assy, Waste Containers and Cart	

Intended Purpose: The BenchMark ULTRA PLUS instrument is intended to automatically stain histological or cytological specimens on microscope slides with specific





immunohistochemistry, immunocytochemistry, or in situ hybridization reagents for *in vitro* diagnostic use.

BenchMark ULTRA PLUS instrument fully automates the processes of baking, deparaffinization, and staining for the qualitative or semi quantitative detection of analytes as an aid in diagnosis by pathologists. The system is intended for use in the anatomic pathology (AP) laboratory environment by trained laboratory personnel who are knowledgeable in histology processes and have basic computer operation skills

Risk Class and Classification Rule: Class A, as per EU Regulation 2017/746, Annex VIII, Rule 5

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

Conformity of the product with EU Regulation 2017/746 and the following EU legislation, which also require an EU Declaration of Conformity, and other applicable EU legislation, has been established.

- Complies with the requirements of Directive 2011/65/EU including amendment of Annex II 2015/863/EU of 31 March 2015 on the restriction of the use of certain hazardous substances according to Annex II (RoHS III)

On behalf of Ventana Medical Systems Inc.

Place: Tucson, AZ 85755, USA

Place: Tucson, AZ 85755, USA

Date: 12 August 2022

Date: 16 August 2022

DocuSigned by:
Jeff Boone
Jeff Boone

DocuSigned by:
Benjamin Curson
Benjamin Curson

Site Head of Quality Function

Site Head of Regulatory Affairs Function

