



# 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:
06396518001 (alternative P/N: 760-099)	OptiView Amplification Kit	761333601379B2
06718663001 (alternative P/N: 860-099)		

**Intended Purpose:** OptiView Amplification Kit may be used in conjunction with the OptiView DAB IHC Detection Kit to increase the staining intensity of mouse and rabbit primary antibodies. The kit is to be used for qualitative staining of formalin-fixed, paraffin-embedded tissue, or frozen tissue on a BenchMark IHC/ISH instrument with VENTANA primary antibodies and ancillary reagents, visualized by light microscopy. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. 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

  
 Benjamin Curson

Site Head of Quality Function

Site Head of Regulatory Affairs Function