

# 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

<b>Part Number:</b>	<b>Product Name:</b>	<b>Basic UDI-DI:</b>
05867088001 (alternative P/N: 790-4517)	Ventana anti-P120 Catenin (98) Mouse Monoclonal Primary Antibody	761333601833B3

**Intended Purpose:** VENTANA anti-p120 catenin (98) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of p120 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

Place: Tucson, AZ 85755, USA

Date:

Date:

DocuSigned by:

*Jeff Boone*

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**Jeff Boone**

Site Head of Quality Function

DocuSigned by:

*Benjamin Curson*

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**Benjamin Curson**

Site Head of Regulatory Affairs Function