



# 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>
05587760001 (alternative P/N: 790-4431)	CONFIRM anti-Cytokeratin 20 (SP33) Rabbit Monoclonal Primary Antibody	761333601185AK

**Intended Purpose:** CONFIRM anti-Cytokeratin 20 (SP33) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of cytokeratin 20 (CK20) 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

Place: Tucson, AZ 85755, USA

Date: 21-Jun-2022

*Jeff Boone*

**Jeff Boone**

Site Head of Quality Function

*Ben Curson*

**Benjamin Curson**

Site Head of Regulatory Affairs Function