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) Manufacturer:	**US-MF-000016993**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**DE-AR-000006262**

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

Digitally signed by Lazari Cristina
Date: 2024.12.02 20:09:24 EET
Reason: MoldSign Signature
Location: Moldova

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: 18-Jul-2022	Date: 19-Jul-2022
Jeff Boone	Ben Curson
Jeff Boone	**Benjamin Curson**
Site Head of Quality Function	Site Head of Regulatory Affairs Function