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:
06478450001 (alternative P/N: 790-4576)	anti-ERG (EPR3864) Rabbit Monoclonal Primary Antibody	761333601233A5

Intended Purpose:	Anti-ERG (EPR3864) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of both wildtype ERG, and truncated ERG resulting from ERG gene rearrangement in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic (IVD) use.
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):

Digitally signed by Lazari Cristina
Date: 2024.12.02 20:16:12 EET
Reason: MoldSign Signature
Location: Moldova

EU Quality Management System Certificate: V12 096981

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-Feb-2022

DocuSigned by:
Jeff Boone
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Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 01-Mar-2022

Ben Curson

Benjamin Curson

Site Head of Regulatory Affairs Function