



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: |
|--|--|----------------------|
| 05277990001 (alternative P/N: 790-2223) 50 tests | CONFIRM anti-Progesterone Receptor (PR) (1E2) Rabbit Monoclonal Primary Antibody | 761333601236AB |
| 05278392001 (alternative P/N: 790-4296) 250 tests | | |

Intended Purpose: CONFIRM anti-Progesterone Receptor (PR) (1E2) Rabbit Monoclonal (IgG) Primary Antibody is intended for laboratory use in the qualitative detection of progesterone receptor (PR) antigen in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer with VENTANA detection kits and ancillary reagents. CONFIRM anti-PR (1E2) antibody is directed against an epitope present on human progesterone receptor protein located in the nucleus of PR positive normal and neoplastic cells. CONFIRM anti-PR (1E2) antibody is indicated as an aid in the management, prognosis, and prediction of therapy outcome of breast carcinoma. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. Prescription use only. 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 devices.



**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

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: 26-Jan-2022

Date: 31-Jan-2022

DocuSigned by:

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Jeff Boone

Site Head of Quality Function

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Benjamin Curson

Site Head of Regulatory Affairs Function