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:
05278406001 (alternative P/N: 790-4324) 50 tests	CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody	761333601237AD
05278414001 (alternative P/N: 790-4325) 250 tests		

Intended Purpose: CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody (CONFIRM anti-ER (SP1) antibody) is intended for laboratory use in the qualitative detection of estrogen receptor (ER) antigen in sections of formalin-fixed, paraffin-embedded breast tissue on a VENTANA automated slide stainer with VENTANA detection kits and ancillary reagents. CONFIRM anti-ER (SP1) antibody is directed against an epitope present on human ER alpha protein located in the nucleus of ER positive normal and neoplastic cells. CONFIRM anti-ER (SP1) antibody is indicated as an aid in the management, prognosis, and prediction of hormone therapy for 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 device.

Digitally signed by Lazari Cristina
Date: 2023.06.28 13:51:14 EEST
Reason: MoldSign Signature
Location: Moldova

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

Date: 26-Jan-2022

DocuSigned by:
Jeff Boone
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Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 31-Jan-2022

DocuSigned by:
Ben Curson
6E68FEBA2C01421...

Benjamin Curson

Site Head of Regulatory Affairs Function