



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: |
|---|--|----------------------|
| 05867061001 (alternative P/N: 790-4509) | VENTANA anti-p63 (4A4) Mouse Monoclonal Primary Antibody | 761333600840AR |

Intended Purpose: VENTANA anti-p63 (4A4) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of the p63 protein 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



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: 22-Feb-2022

Date: 01-Mar-2022

DocuSigned by:
Jeff Boone

Ben Curson

Jeff Boone

Benjamin Curson

Site Head of Quality Function

Site Head of Regulatory Affairs Function