# 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.**<br>**1910 E Innovation Park Drive**<br>**Tucson, AZ 85755, USA** |
| Single Registration Number (SRN) Manufacturer: | **US-MF-000016993** |
| Authorized Representative: | **Roche Diagnostics GmbH**<br>**Sandhofer Strasse 116**<br>**68305 Mannheim**<br>**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: |
|---|---|---|
| 05278252001 (alternative P/N: 790-2931) | CONFIRM anti-CD68 (KP-1) Primary Antibody | 761333601225A6 |

| | |
|---|---|
| **Intended Purpose:** | CONFIRM anti-CD68 (KP-1) Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD68 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)<br>Ridlerstraße 65<br>80339 MÜNCHEN<br>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 20:08:45 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

Date: 27 September 2022

DocuSigned by:
Jeff Boone
DBC56B8025BB4D8...

**Jeff Boone**

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 22 September 2022

DocuSigned by:
Benjamin Curson
6E68FEBA2C01421...

**Benjamin Curson**

Site Head of Regulatory Affairs Function