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:
05269806001 (alternative P/N: 760-500)	ultraView Universal DAB Detection Kit	7613336012229Y

Intended Purpose:	ultraView Universal DAB Detection Kit is an indirect, biotin-free system for detecting mouse IgG, mouse IgM and rabbit primary antibodies. The kit is intended to identify targets by immunohistochemistry in sections of formalin-fixed, paraffin-embedded tissue, or frozen tissue, that are stained on the 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 product is intended for in vitro diagnostic (IVD) use.
Risk Class:	Class A
Common Specifications:	Not applicable as no Common Specifications exist for the concerned device.

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

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