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:
05266114001 (alternative P/N: 760-080)	Amplification Kit	7613336012309X

Intended Purpose:	Ventana Medical Systems, Inc.'s (Ventana) Amplification Kit may be used in conjunction with VENTANA detection kits to increase the signal intensity of weak staining mouse and rabbit primary antibodies. The kit is to be used for qualitative staining of formalin-fixed, paraffin-embedded tissue, frozen tissue or cytological preparations on VENTANA automated slide stainers with VENTANA primary antibodies, detection kits and ancillary reagents. 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: 29-Mar-2022

Jeff Boone

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 28-Mar-2022

Ben Curson

Benjamin Curson

Site Head of Regulatory Affairs Function