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:
05250927001 (alternative P/N: 1637600)	Inline User-Fillable Kit	761333602231A8
05250935001 (alternative P/N: 1637700)	Prep Kit	761333602229AM
07475144001 (alternative P/N: 1637701)	Light Protective Prep Kit	761333602230A6

Intended Purpose: The Inline User-Fillable Kit, Prep Kit, and Light Protective Prep Kit are used on BenchMark IHC/ISH instruments to dispense reagents and solutions during laboratory use. These products are used with VENTANA dispenser cards and associated instrument software for device registration.

The Inline User-Fillable Kit, Prep Kit, and Light Protective Prep Kit are not validated for re-use with a second VENTANA dispenser card, or any use other than what is described in the Instrument's User Guide or Operator's Manual.

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: 12-May-2022

Jeff Boone

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 12-May-2022

Ben Curson

Benjamin Curson

Site Head of Regulatory Affairs Function