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:
05278511001 (alternative P/N: 800-092)	VENTANA ISH iVIEWBlue Detection Kit	761333601834B5

Intended Purpose: VENTANA ISH iVIEW Blue Detection Kit is an indirect biotin streptavidin system for the detection of fluorescein-labeled probes. The kit is intended to identify targets by in situ hybridization in sections of formalin-fixed, paraffin-embedded tissue that are stained on a BenchMark IHC/ISH instrument. 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