



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) **US-MF-000016993**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH**
Sandhofer Strasse 116
68305 Mannheim
Germany

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

This declaration is issued under the sole responsibility of Ventana Medical Systems Inc.

Product Information

Part Number:	Product Name:	Basic UDI-DI:
08318832001 (alternative P/N: 760-512)	VENTANA Red ISH DIG Detection Kit	7613336012039U

Intended Purpose: The VENTANA Red ISH DIG Detection Kit is an indirect system for detecting DIG-labeled targets. The kit is intended to identify targets by chromogenic red in situ hybridization (ISH) in sections of formalin-fixed, paraffin-embedded tissue that are stained on BenchMark IHC/ISH instruments.
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


Place: Tucson, AZ 85755, USA

Date: 29-Mar-2022

Date: 28-Mar-2022


Jeff Boone

Site Head of Quality Function


Benjamin Curson

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