

Roche

# 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:
05264839001 (alternative P/N: 650-010)	LCS (Predilute)	7613336012209U

**Intended Purpose:** LCS (Predilute) is a prediluted coverslip solution intended for laboratory use as a barrier between the aqueous reagents and the air. This barrier prevents evaporation, thereby providing a stable aqueous environment for the immunohistochemistry, immunocytochemistry, or in situ hybridization reactions on BenchMark GX and BenchMark XT instruments. This reagent is intended for *in vitro* diagnostic 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: 22-Feb-2022

Date: 01-Mar-2022

DocuSigned by:

*Jeff Boone*  
Jeff Boone

*Ben Curson*

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Site Head of Quality Function

Site Head of Regulatory Affairs Function

