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:
05424534001 (alternative P/N: 650-210)	ULTRA LCS (Predilute)	7613336012219W

Intended Purpose: ULTRA 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 carried out on the BenchMark ULTRA instrument. This reagent 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: 22-Feb-2022

DocuSigned by:
Jeff Boone
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Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 01-Mar-2022

Ben Curson

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