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:
05424569001 (alternative P/N: 950-224)	ULTRA Cell Conditioning Solution (ULTRA CC1)	761333601915B6

Intended Purpose: ULTRA Cell Conditioning Solution (ULTRA CC1) is a pre diluted solution intended for laboratory use as a pretreatment step in the processing of formalin-fixed, paraffin-embedded tissue samples, and cytological specimens for immunohistochemistry, in situ hybridization, and immunocytochemistry applications on a BenchMark ULTRA 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: 22-Feb-2022

DocuSigned by:
Jeff Boone

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 01-Mar-2022

Ben. Curson.

Benjamin Curson

Site Head of Regulatory Affairs Function