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** **D-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:
05342716001 (alternative P/N 750-600)	BenchMark ULTRA Instrument	761333602109AA

Accessories		
Part Number	**Product Name**	**Basic UDI-DI**
05424585001 (alternative P/N 1697400)	Kit, accessory 1, ULTRA	761333602109AA
05424577001 (alternative P/N 2505700)	Kit, accessory 2, ULTRA	
05250986001 (alternative P/N 1650800)	Assembly, waste container and cart	

Intended Purpose: The BenchMark ULTRA instrument is intended to automatically stain histological or cytological specimens on microscopic slides with specific immunohistochemistry, immunocytochemistry, or in situ hybridization reagents for in vitro diagnostic (IVD) use. The BenchMark ULTRA instrument fully automates the process of baking, deparaffinization, and staining of the qualitative or semi quantitative detection of analytes as an

	aid in diagnosis by pathologists. The system is intended for use in the anatomic pathology (AP) laboratory environment by trained laboratory personnel who are knowledgeable in histology processes and have basic computer operation skills
Risk Class and Classification Rule:	Class A, as per EU Regulation 2017/746, Annex VIII, Rule 5
Common Specifications:	Not applicable as no Common specifications exist for the concerned device

Conformity of the product with EU Regulation 2017/746 and the following EU legislation, which also require an EU Declaration of Conformity, and other applicable EU legislation, has been established.

- Complies with the requirements of Directive 2011/65/EU including amendment of Annex II 2015/863/EU of 31st March 2015 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

On behalf of Ventana Medical Systems Inc.

Place: Tucson, AZ 85755, USA

Date: 09 November 2022

DocuSigned by:
Jeff Boone

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 10 November 2022

DocuSigned by:
Benjamin Curson

Benjamin Curson

Site Head of Regulatory Affairs Function