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:
09576797001	BenchMark ULTRA PLUS Instrument	761333602634B2

Install Components/Accessories		
Part Number	**Product Name**	**Basic UDI-DI**
08706905001	BenchMark ULTRA PLUS Accessory Kit	761333602634B2
08706956001	BenchMark ULTRA PLUS Bottle ship kit	
08270635001	BenchMark ULTRA PLUS Assy, Waste Containers and Cart	

Intended Purpose: The BenchMark ULTRA PLUS instrument is intended to automatically stain histological or cytological specimens on microscope slides with specific

	immunohistochemistry, immunocytochemistry, or in situ hybridization reagents for *in vitro* diagnostic use. BenchMark ULTRA PLUS instrument fully automates the processes of baking, deparaffinization, and staining for 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 31 March 2015 on the restriction of the use of certain hazardous substances according to Annex II (RoHS III)

On behalf of Ventana Medical Systems Inc.

Place: Tucson, AZ 85755, USA

Date: 12 August 2022

DocuSigned by:
Jeff Boone
[illegible]

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 16 August 2022

DocuSigned by:
Benjamin Curson
[illegible]

Benjamin Curson

Site Head of Regulatory Affairs Function