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:
05894662001 (alternate P/N 750-850)	Benchmark GX Staining Module	761333601921AZ
05894620001 (alternate P/N 750-851)	Benchmark GX AFM, 120V Assembly	
05894638001 (alternate P/N 750-861)	Benchmark GX AFM, 230V Assembly	
05894646001 (alternate P/N 750-871)	Benchmark GX AFM, 100V Assembly	

Intended Purpose:

The BenchMark GX 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 (IVD) use.

The BenchMark GX instrument fully automates the process 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 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
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Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 10 November 2022

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Site Head of Regulatory Affairs Function