EU Declaration of Conformity

as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices

Manufacturer:	Ventana Medical Systems Inc.
Address:	1910 E Innovation Park Drive Tucson, AZ 85755, USA
Single Registration Number:	US-MF-000016993
Authorized Representative:	Roche Diagnostics GmbH
Address:	Sandhofer Strasse 116 68305 Mannheim Germany
Single Registration Number:	DE-AR-000006262

Ventana Medical Systems Inc., declares, under the sole responsibility, that the product/the product line

Product Name	Cat. No.	Basic UDI-DI
Benchmark GX Staining Module	05894662001 (alternate P/N 750-850)	761333602033A2
Benchmark GX AFM, 120V Assembly	05894620001 (alternate P/N 750-851)	
Benchmark GX AFM, 230V Assembly	05894638001 (alternate P/N 750-861)	
Benchmark GX AFM, 100V Assembly	05894646001 (alternate P/N 750-871)	

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.

Intended Use:

Risk Class:	☒ A ☐ B ☐ C ☐ D
Conformity Route:	☒ Self-Declaration of Conformity (Class A)
Certificates:	☒ NA
Other:	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 of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).
Notified Body (NB) Name:	NA
NB Address:	NA
NB Ident. No.:	NA

to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Tucson, AZ, 85755, USA 5 November 2025

Ventana Medical Systems, Inc.

ppa./*on behalf of the company*

Signed by:
Susan Hollandbeck
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Susan Hollandbeck
Site Head of Quality Function

ppa./*on behalf of the company*

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Jennifer Tucker
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