# 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.

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| Manufacturer: | **Ventana Medical Systems Inc.**<br>**1910 E Innovation Park Drive**<br>**Tucson, AZ 85755, USA** |
| Single Registration Number (SRN) Manufacturer: | **US-MF-000016993** |
| Authorized Representative: | **Roche Diagnostics GmbH**<br>**Sandhofer Strasse 116**<br>**D-68305 Mannheim**<br>**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 |
|---|---|---|
| 06468373001 | Benchmark Special Stains Stainer Module | 761333602512AK |

| Accessories | | |
|---|---|---|
| **Part Number** | **Product Name** | **Basic UDI-DI** |
| 06468357001 | Benchmark Special Stains Waste Module 120V | 761333602512AK |
| 06468365001 | Benchmark Special Stains Waste Module 230V | |
| 06468349001 | Benchmark Special Stains Waste Module 100V | |
| 06563716001 | Reagent Tray, BMK Special Stains | |
| 06564909001 | Accessory Kit BMK Special Stains | |

**Intended Purpose:** The BenchMark Special Stains instrument is intended to automatically stain histologic sections of formalin-fixed, paraffin-embedded (FFPE) specimens on microscope slides with specific special stains histochemistry reagents for in vitro diagnostic (IVD) use. The BenchMark Special Stains instrument fully automates the process of baking, deparaffinization, and staining for the qualitative detection of targets 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

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| **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
[illegible]

**Jeff Boone**

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 10 November 2022

DocuSigned by:
Benjamin Curson
[illegible]

**Benjamin Curson**

Site Head of Regulatory Affairs Function