



# 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) **US-MF-000016993**  
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH**  
**Sandhofer Strasse 116**  
**68305 Mannheim**  
**Germany**

Single Registration Number (SRN) **DE-AR-000006262**  
Authorized Representative:

This declaration is issued under the sole responsibility of Ventana Medical Systems Inc.

## Product Information

Part Number:	Product Name:	Basic UDI-DI:
05277965001 (alternative P/N: 790-2208)	Hematoxylin II	761333601224A4

**Intended Purpose:** Hematoxylin II is a modified Mayer's hematoxylin intended for laboratory use in staining cellular nuclei on slides containing cells from frozen tissue, or formalin fixed, paraffin-embedded tissue on a BenchMark IHC/ISH instrument. This reagent is intended as a counterstain to immunohistochemistry, and in situ hybridization applications. This reagent is intended for in vitro diagnostic use.

**Risk Class:** Class A

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.

Conformity of the product with EU Regulation 2017/746 and other applicable EU legislation has been established.

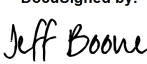
On behalf of Ventana Medical Systems Inc.

Place: Tucson, AZ 85755, USA

Place: Tucson, AZ 85755, USA

Date: 22-Feb-2022

Date: 01-Mar-2022

DocuSigned by:  
  
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**Jeff Boone**

Site Head of Quality Function



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