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** **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:
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

Date: 22-Feb-2022

DocuSigned by:
Jeff Boone
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Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 01-Mar-2022

Ben Curson

Benjamin Curson

Site Head of Regulatory Affairs Function

Digitally signed by Lazari Cristina
Date: 2024.12.02 20:25:12 EET
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