



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:
05272017001 (alternative P/N: 780-2218)	Red Counterstain II	761333601907B7

Intended Purpose: Red Counterstain II is intended to aid microscopic bright field observation for in situ hybridization applications. Red Counterstain II is for use with formalin-fixed, paraffin-embedded tissue on a BenchMark IHC/ISH instrument.
 This reagent is intended for in vitro diagnostic (IVD) 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: 29-Mar-2022

Date: 28-Mar-2022

Jeff Boone

Ben Curson

Jeff Boone

Benjamin Curson

Site Head of Quality Function

Site Head of Regulatory Affairs Function

