



# 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:
05273331001 (alternative P/N: 780-4149)	ISH Protease 3	761333601910AU

**Intended Purpose:** ISH Protease 3 is intended for enzymatic digestion of formalin-fixed, paraffin-embedded tissue sections, or whole cell preparations on a BenchMark IHC/ISH instrument. This reagent removes protein that surrounds the target nucleic acid sequences of interest during in situ hybridization applications.  
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**

Site Head of Quality Function

**Benjamin Curson**

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