

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:
05266688001 (alternative P/N: 760-2018)	Protease 1	761333601904AZ

Intended Purpose: Protease 1 is an endopeptidase (alkaline protease) of the serine protease

family and cleaves proteins in the tissue section, allowing primary antibodies to recognize and bind epitope(s). The reagent is intended for enzymatic digestion of sections of routine 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: Date: 28-Mar-2022

Jeff Boone Ben Curson

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Site Head of Quality Function Site Head of Regulatory Affairs Function