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:
06695248001 (alternative P/N: 805-4713) 06695256001 (alternative P/N: 825-4713)	CINtec® p16 Histology	761333601839BF

Intended Purpose:	CINtec p16 Histology is an immuno-histochemistry assay for the qualitative detection of the p16INK4a protein on formalin-fixed, paraffin-embedded tissue sections prepared from cervical biopsies. It is indicated to be used in conjunction with H&E stained slides prepared from the same cervical tissue specimen as an aid to increase diagnostic accuracy and inter-observer agreement in the diagnosis of high grade cervical intraepithelial neoplasia.
Risk Class:	Class C
Common Specifications:	Not applicable as no Common Specifications exist for the concerned device.
Name, Address and Identification number of the Notified Body:	TÜV SÜD Product Service GmbH (No. 0123) Ridlerstraße 65 80339 MÜNCHEN Germany

Conformity Assessment was established through the procedure described in Annex IX of EU Regulation 2017/746, including an assessment of the Technical Documentation as described in Annex IX, Chapter II. This declaration is supported by the following certificate(s):

EU Quality Management System Certificate: V12 0969810003

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: 27 November 2022

DocuSigned by:
Jeff Boone
D9C3B8025BB4D8...

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 22 November 2022

DocuSigned by:
Benjamin Curson
6E68FEBA2C01421...

Benjamin Curson

Site Head of Regulatory Affairs Function