

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:
05278694001 (alternative P/N: 800-2845)	Alu Positive Control Probe	761333601869BQ

Intended Purpose: Alu Positive Control Probe is a cocktail of oligonucleotide probes labeled with fluorescein that is intended for the laboratory use as a positive control to determine the preservation of DNA during specimen collection, processing, fixation and handling, in sections of formalin-fixed, paraffin-embedded tissue on a BenchMark IHC/ISH instrument. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

Risk Class: Class B

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 096981 0003





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: 27 october 2022

Date: 26 october 2022

DocuSigned by:

Jeff Boone

Jeff Boone

Site Head of Quality Function

DocuSigned by:

Benjamin Curson

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Site Head of Regulatory Affairs Function

