



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:
06364497001 (alternative P/N: 790-4536)	VENTANA Basal Cell Cocktail	761333601383AR
06419445001 (alternative P/N: 790-1010)	(34βE12+p63)	

Intended Purpose: VENTANA Basal Cell Cocktail (34βE12+p63) is an antibody cocktail of anti-p63 (4A4) and anti-keratin (34βE12) mouse monoclonal antibodies. VENTANA Basal Cell Cocktail (34βE12+p63) is intended for laboratory use in the qualitative immunohistochemical detection of p63 and cytokeratin 5 in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument.

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 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

Date: 18-Jul-2022

Jeff Boone

Jeff Boone

Site Head of Quality Function

Place: Tucson, AZ 85755, USA

Date: 19-Jul-2022

Ben Curson

Benjamin Curson

Site Head of Regulatory Affairs Function