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**TITLE: D129031 Rev. 2 – Quality Control Specification for Benchmark Special Stains Deparaffinization Solution (10X) PN 860-036**

**Product Name** Benchmark Special Stains Deparaffinization Solution (10X)  
**Ventana**  REF 860-036  
**Roche Number** 06523102001

**Visual Inspection** The reagent must be clear and free of turbidity.  
 The reagent must be free of foreign material and substantially free of particulate matter.

  
 Quality Department Manager 19-Jan-2021  
 Date

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## Certificate of Analysis

**Product name**

BMK SPEC STAINS DEPAR SOLUTION (10X)

**Material No.**

06523102001

**Lot No.**

J06734Z

**Date of Manufacturing**

2022-03-29

**Expiry Date**

2024-03-28

**Parameter****Result****Unit**

Visual Inspection

Pass

Reagent must be clear, and free of turbidity.

Reagent must be free of foreign material and substantially free of intrinsic particulate matter.

This lot meets our specification

**Disposition by**

Antonio Reyes

This certificate is a computer printout and has therefore not been signed by hand.

**Issue date** 2022-04-06

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Ventana Medical Systems, Inc.  
1910 Innovation Park Drive  
Tucson, Arizona 85755  
Phone: + 1 800 227 2155  
<http://www.ventana.com>

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**TITLE: DDS-0463-3 Rev B - Device Description and Specification for BenchMark Special Stains Deparaffinization Solution (10X)**

## 1.1. Device Description and Specification

- a. Product or Trade Name and a General Description of the Device including its Intended Purpose and Intended Users

<b>Product Name</b>	BenchMark Special Stains Deparaffinization Solution (10X)
<b>General Description</b>	BenchMark Special Stains Deparaffinization Solution (10X) is a reagent used to solubilize paraffin during the deparaffinization process for slides containing formalin-fixed, paraffin-embedded tissues during special stains procedures on a BenchMark Special Stains instrument in laboratory use.
<b>Intended Purpose</b>	See Instructions for Use (Method Sheet) 1011223EN
<b>Intended Users</b>	

- b. Basic UDI-DI (Part C, Annex VI)

<b>Product Part Number</b>	06523102001
<b>Product Alternative Part Number</b>	860-036
<b>Basic UDI-DI</b>	761333601718B2

- c. Intended Purpose of the Device

See Instructions for Use (Method Sheet) 1011223EN. All elements of the intended purpose (per IVDR ANNEX I, Chapter III, Section 20.4.1.) are contained within the Intended Use section of the Method Sheet.

- d. Description of the Principle of the Assay Method

See “Principle of the Procedure” section in the Instructions for Use (Method Sheet) 1011223EN.

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**e. Rationale for the Qualification of the Product as a Device**

BenchMark Special Stains Deparaffinization Solution (10X) meets the definition of an ‘in vitro diagnostic medical device’ as it is a reagent product intended to be used in combination with other in vitro diagnostic medical devices to assist in the examination of formalin-fixed, paraffin-embedded tissue specimens derived from the human body. Specifically, it is intended to solubilize paraffin during the deparaffinization process for slides.

**f. Risk class of the Device and the Justification for the Classification Rule(s) Applied (Annex VIII)**

The product is classified as Class A according to the classification rules laid out in Annex VIII of the IVD Regulation (EU) 2017/746.

<b>Class</b>	A
<b>Rule</b>	Rule 5 (a) products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for in vitro diagnostic procedures relating to a specific examination

**g. Components and Reactive Ingredients**

See “Material Provided” section in the Instructions for Use (Method Sheet) 1011223EN.

**h. Specimen Collection**

Recommended specimen preparation is described in the appropriate staining kit Instructions for Use (Method Sheet).

**i. For Instruments of Automated Assays: Description of the appropriate assay characteristics or dedicated assays**

This section does not apply for BenchMark Special Stains Deparaffinization Solution (10X) as it is a reagent product.

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- j. For Automated Assays: Description of the appropriate instrumentation characteristics or dedicated instrumentation

BenchMark Special Stains Deparaffinization Solution (10X) has been developed for use in the automated staining process on the BenchMark Special Stains instrument. Refer to the appropriate staining kit method sheet for the recommended staining protocol and to the Instrument’s User Guide for detailed instructions and additional protocol options as indicated in the Instructions for Use (Method Sheet) 1016871EN.

- k. Description of any Software to be used with the Device

BenchMark Special Stains Deparaffinization Solution (10X) has been developed for use on BenchMark Special Stains instrument in combination with BenchMark Special Stains reagents and accessories. Refer to the appropriate staining kit method sheet for the recommended staining protocol and to the instrument User Guide for detailed instructions and additional protocol options. The diluted BenchMark Special Stains Deparaffinization Solution (10X) is applied automatically as required for the procedure being run. The parameters for the automated procedures can be displayed, printed, and edited according to the procedure in the Instrument’s User Guide. Platform operating software is reported on in the Benchmark Special Stainer system TDF-0451.

- l. Configurations/Variants of the Device

This section is not applicable, as BenchMark Special Stains Deparaffinization Solution (10X) does not have various configurations or variants.

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m. Accessories or other Devices Intended to be used in Combination with the Device

BenchMark Special Stains Deparaffinization Solution (10X) does not have any required accessories.

Materials that are required or recommended for use with BenchMark Special Stains Deparaffinization Solution (10X) but are sold separately are listed in the “Materials Required but not Provided” section in the Instructions for Use (Method Sheet) 1011223EN.

**1.2. Reference to Previous and Similar Generations of the Device**

a. Overview of the Previous Generation(s) of the Device Produced by the Manufacturer

BenchMark Special Stains Deparaffinization Solution (10X) does not have previous generation(s) of the device produced by Ventana Medical Systems Inc.

b. Overview of Identified Similar Devices

The following similar devices were identified for BenchMark Special Stains Deparaffinization Solution (10X).

<b>Company</b>	<b>Product Name</b>	<b>Product Ventana Part Number</b>	<b>Product Roche Material Number</b>
Roche	EZ Prep Concentrate (10X)	950-102	05279771001

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