

## EC Declaration of Conformity

*I, the undersigned, hereby declare that the products specified below conform to Annex III of Directive 98/79/EC of the European Parliament and Council of 27 October 1998, on in-vitro diagnostic medical devices (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market); and*

*to Annex VI of Directive 2011/65/EU of the European Parliament and Council of 8 June 2011 on the restriction of the use of certain hazardous substances according Annex II (lead, mercury, hexavalent chromium, cadmium, polybrominated biphenyls and polybrominated diphenyl ethers) in electrical and electronic equipment (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market).*

Manufacturer: Ventana Medical Systems, Inc.

Address: 1910 E. Innovation Park Drive  
Tucson, AZ USA 85755

European Authorized Representative: ROCHE DIAGNOSTICS GmbH  
Sandhofer Strasse 116  
D-68305 Mannheim  
Germany

Manufacturing Sites: See attachment

Product name: BenchMark GX

Ventana P/N: 750-850  
Roche P/N: 05894662001

Classification: General IVD  
Technical Data File: TDF- 0033  
Date of First CE Marking: 2008

Name of Authorized Signatory: Deepshikha Bhandari  
Vice President, Regulatory Affairs

Signature: Deepshikha Bhandari Date: 22-JULY-2016

The BenchMark GX includes the following System Components:

System Component	Ventana P/N	Roche Part #	Component Manufacturing site
BenchMark GX Stainer	750-850	05894662001	Ventana Medical Systems, Inc. 1910 E Innovation Park Drive Tucson, AZ 85755 USA
BenchMark GX AFM (230 V)	750-861	05894638001	Sanmina Coporation (Plant 2593), Carretera Guadalajara-Chapala Km 15.5 No. 29, Col. Zapote del Valle, Tlajomuclo de Zúñiga, Mexico, CP. 45640.
BenchMark GX AFM (120 V)	750-851	05894620001	
BenchMark GX AFM (100 V)	750-871	05894646001	
BenchMark GX waste cabinet	750-872	05894654001	
Assembly, BenchMark GX Drawer	2530701	05894689001	