

## 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).*

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 Site: Tucson, AZ USA

Product name: Iron Staining Kit

Ventana P/N: 860-009  
Roche P/N: 05279259001

Classification: General IVD  
Technical Data File: TDF-0066  
Date of First CE Marking: 16-May-2007

Name of Authorized Signatory: Peter Martin  
Vice President, Regulatory Affairs

Signature:  \_\_\_\_\_ Date: 22-Aug-2018