

## Declaration of Conformity

as per Annex III of Directive 98/79/EC of the European Parliaments and Council of 27 October 1998

Manufacturer: Roche Diagnostics GmbH  
Sandhofer Strasse 116  
68305 Mannheim  
Germany

*Roche Diagnostics GmbH declares that the product/the product line*

*Product name:* **VENTANA HER2 Dual ISH DNA Probe Cocktail**

*Roche Id.-No.:* **08314373001**

*Ventana Id.-No.:* **800-6043**

*to which this declaration relates fulfils the requirements 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).*

Mannheim, 16 April 2019

Roche Diagnostics GmbH

*ppa./on behalf of the company*



Ralf Zielenski  
Head of Quality  
Centralised and Point of Care Solutions

*ppa./on behalf of the company*

i.V. Stefan Grigarczik



Dr. Stefan Scheib  
Director Global Regulatory Affairs  
Centralised and Point of Care Solutions

*Kontaktadresse/Contact address:* Roche Diagnostics GmbH  
Abt./Dept. Global Regulatory Affairs  
Sandhofer Strasse 116  
68305 Mannheim  
Germany