

## 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: **CINtec p16 Histology**

Roche Id.-No.: **06695221001**

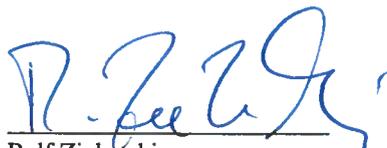
Ventana Id.-No.: **705-4713**

*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, 20 September 2018

Roche Diagnostics GmbH

*ppa./on behalf of the company*



Ralf Zielenki  
Head of Quality  
Centralised and Point of Care Solutions

*ppa./on behalf of the company*



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

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