



# EC Declaration of Conformity

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

**Manufacturer:** Ventana Medical Systems, Inc.  
1910 E. Innovation Park Drive  
Tucson, AZ 85755  
USA

**European Authorized Representative:** Roche Diagnostics GmbH  
Sandhofer Strasse 116  
D-68305 Mannheim  
Germany

**Manufacturing Site:** Ventana Medical Systems, Inc.  
1910 E. Innovation Park Drive  
Tucson, AZ 85755  
USA

Ventana Medical Systems, Inc. declares that the in vitro diagnostic medical device:

**Product Name:** CONFIRM anti-PAX5 (SP34) Rabbit Monoclonal Primary Antibody  
**Ventana P/N:** 790-4420  
**Roche P/N:** 05552729001  
**Classification:** General IVD  
**Technical Data File:** TDF-0627

Complies with the requirements of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Tucson, AZ

Date: 16-Apr-2021

**Benjamin Curson**  
Ad Interim Head of the Regulatory Affairs