



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