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-p53 (DO-7) Primary Antibody**
Ventana P/N:	**800-2912**
Roche P/N:	**05278775001**
Classification:	**General IVD**
Technical Data File:	**TDF-0098**

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: 26-May-2021

Benjamin Curson
Ad Interim Head of Regulatory Affairs