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 Sites:

Ventana Medical Systems, Inc.	Roche Diagnostics (Suzhou) Ltd.
1910 E. Innovation Park Drive	No. 259 Zhongyuan Road
Tucson, AZ 85755	215028 Suzhou, Jiangsu
USA	Peoples Republic of China

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

Product Name:	LCS (Predilute)	LCS (Predilute)
Ventana P/N:	650-010	651-010
Roche P/N:	05264839001	05264839214
Classification:	General IVD	General IVD
Technical Data File:	TDF-0044-1	TDF-0044-1

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: 22-Oct-2021

Benjamin Curson
Ad-Interim Head of Regulatory Affairs