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:	**VENTANA PD-L1 (SP263) Assay**
Roche Id.-No.:	**07419821001**
Ventana Id.-No.:	**741-4905**

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, 28 April 2022

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Ralf Zielenski
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Ralf Zielenski
Head Q&R Compliance, PRRC RDG
Centralised and Point of Care Solutions

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DocuSigned by:
Stefan Scheib
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Dr. Stefan Scheib
Network Lead Core Lab, Global Regulatory Affairs
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