

# CE DECLARATION OF CONFORMITY

Part numbers: RT2951 (10 cassettes), RT2952 (25 cassettes)  
Product name: AMP Rapid Test SARS-CoV-2 Ag  
IVD-classification acc. to directive 98/79/EC: other IVD

We, AMEDA Labordiagnostik GmbH, Krenngasse 12, 8010 Graz, Austria, declare under sole responsibility that the products described above are in compliance with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices and that the following harmonized standards have been resp. are applied in development, design and manufacturing.

<b>Instructions for Use</b>	EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
<b>Performance</b>	EN 13612:2002	Performance evaluation of IVD medical devices
<b>Stability</b>	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
<b>Symbols</b>	EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
<b>Risk analysis</b>	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices

The products are CE marked.

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