CE DECLARATION OF CONFORMITY

Part numbers:	RT3950 (1 cassette), RT3951 (10 x 1 cassette), RT3952 (20 cassettes)
Product name:	AMP Rapid Test SARS-CoV-2 Ag Sputum
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.

Instructions for Use	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
Performance	EN 13612:2002	Performance evaluation of IVD medical devices
Stability	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
Symbols	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
Risk analysis	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices

The products are CE marked.

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Graz - 11.01.2021

Gerald Herfort
COO