

Declaration of Conformity


File name / Revision No.	CE-DOC-TAMAK / 1.0
Product name	TAmiRNA SARS-CoV-2 Antibody Test (Lateral Flow Method)
Product family:	Lateral flow Test
Product number:	TAMAK-10 – 10 Tests per Kit TAMAK-50 – 50 Tests per Kit
UDI if available:	Not applicable
if applicable, Version:	Not applicable
Product category:	In-vitro diagnostic device for professional use
Product classification:	IVD general class, non-listed product according to Annex II of the Directive 98/79

We, TAmiRNA declare in own responsibility that the products described above as delivered are in compliance with directive 98/79 EC and the Austrian medical device Law BGBl 657/1996 in the actual version and the requirements of the quality management system of the harmonized standards EN ISO 13485:2016 and are conform with the essential requirements of Annex I and other applicable articles of the directive 98/79 EC.

Conformity Assessment procedure:	EC Directive 98/79 EC Annex III
Notified Body if consulted:	Not applicable
Quality Management System following:	EN ISO 13485:2016
Certification body:	Not applicable
Certification Registry Number and Validity:	Not applicable
Applicable standards:	EN ISO 14971:2019 EN ISO 62336:2017

The products are CE marked.

Vienna, 03.03.2021



Matthias Hackl
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Address

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Contact

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Company Facts

UID: ATU68320738
FN / commercial registry no: 406620
Place of jurisdiction: HG Wien

Banking

SPK Herzogenburg-Neulengbach
IBAN AT34 2021 9000 2107 3911
BIC SPHEAT21XXX

Revision History

Version	Revision History	Author	Date
1.0	Creation	Elisabeth Semmelrock	Jan 2021

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