abionic

DECLARATION OF CONFORMITY

IVD CAPSULE COVID-19-SS

Month/Year	12/2021
Manufacturer:	Abionic SA
Address:	Route de la Corniche 5 CH-1066 Epalinges Switzerland
Product:	IVD CAPSULE COVID-19-SS
Basic UDI-DI:	7649996894P02DNQ
Type:	In-vitro diagnostic SARS-COV-2 nucleocapsid antigen test
Product Nr. (models):	P02.00047
GMDN:	64829
Intended use:	The IVD CAPSULE COVID-19-SS is a single use, rapid in vitro diagnostic test intended for the qualitative detection of SARS-CoV-2 viral nucleocapsid antigens in saliva from individuals suspected of SARS-CoV-2 infection. The IVD CAPSULE COVID-19-SS is intended to be used in conjunction with the abioSCOPE 2.0 in vitro diagnostic test system by lay users testing themselves or other individuals.
Conformity Assessment Route:	The declaration of conformity is issued under the sole responsibility of Abionic. The in vitro diagnostic test covered by the present CE declaration is in conformity with the EEC directive 98/79/EC (in vitro diagnostic medical devices October 27th, 1998). The in-vitro medical device is classified as In Vitro Diagnostic (Other / General Device) and fulfils the essential requirements according to directive 98/79/EC.
CE Marking:	CE

The product has been developed, produced and tested within a Quality Management System according to ISO 13485:2016 issued by BSI (NB 2797) and annex I section 3 of directive 98/79/EC.All supporting documentation is retained at the premises of the manufacturer.

Place, Date: Lausanne, December 23rd, 2021

Authorized Signatures:

Dr. Nicolas Durand, CEO

Dr. Iwan Märki, CTO