abionic

DECLARATION OF CONFORMITY

abioSCOPE 2.0

Month/Year	05/2022
Manufacturer:	Abionic SA
SRN:	----------
Address:	Biopôle, Alanine Building Route de la Corniche 5 CH-1066 Epalinges Switzerland
Authorised Representative:	Medidee Services (Deutschland) GmbH
Address:	Hohnenweg 9 D-78098 Triberg im Schwarzwald Germany
Product:	Diagnostic device
Basic UDI-DI:	7649996894P01ANF
Type:	abioSCOPE 2.0
Product Nr. (models):	P01.00007 (A04.00006)
Classification:	A
GMDN:	57869
Intended use:	The abioSCOPE is a table top diagnostic device that measures analytes in biological samples, using test- specific capsules (IVD CAPSULE) intended for use with this instrument.
Notified Body Name:	BSI Group, The Netherlands B.V.
Notified Body Address:	Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands
Notified Body ID N°:	NB 2797
Conformity Assessment Route:	Abionic SA uses the following procedures for the CE-marking of their products according to the EU regulation **2017/746 on in vitro diagnostic medical devices**. Class A: EC conformity declaration according to annex IX, chapters I.
CE Marking:	CE

This declaration of conformity is issued under the sole responsibility of Abionic SA.

We hereby declare that the product specified above complies with the EU regulation (IVDR):

2017/746 (in vitro diagnostic medical devices, 5th April 2017)

This declaration is supported by the Quality System approval to ISO 13485:2016 issued by BSI (NB 2797).

All supporting documentation is retained at the premises of the manufacturer.

Place, Date: Epalinges, 25.05.2022

Authorized Signatures:

Dr. Nicolas Durand, CEO

Dr. Iwan Märki, CTO

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Supplementary Information to CE certificate

Manufacturer: Abionic SA
Address: Biopôle, Alanine Building
Route de la Corniche 5
CH-1066 Epalinges
Switzerland

History of certificate:

Date:	Product Nr.	Product name:	Action:
10/2019	P01.00007.001 (A04.00006.001)	abioSCOPE 2.0	First Issue
01/2020	P01.00007.002 (A04.00006.002)	abioSCOPE 2.0	- Added ethernet functionality - Added EMC compatibility to IEC 60601-1-2:2014
03/2020	P01.00007.002 (A04.00006.003)	abioSCOPE 2.0	- Software update adding functionalities
07/2020	P01.00007.002 (A04.00006.004)	abioSCOPE 2.0	- Software update adding functionalities
09/2020	P01.00007.002 (A04.00006.005)	abioSCOPE 2.0	- Change of the painting areas on the tray cover
02/2021	P01.00007.002 (A04.00006.006)	abioSCOPE 2.0	- Software update adding functionalities
07/2021	P01.00007.002 (A04.00006.007)	abioSCOPE 2.0	- Change of the tray coating
09/2021	P01.00007.002 (A04.00006.008)	abioSCOPE 2.0	- Software update adding functionalities and SARS-CoV-2 antigen measurement
12/2021	P01.00007.002 (A04.00006.009)	abioSCOPE 2.0	- Software update adding functionalities
05/2022	P01.00007.002 (A04.00006.009)	abioSCOPE 2.0	IVDR CE declaration (class A)

Associated products:

The certificate referred to above is associated to the following devices and components:

Ref. Nr.:	Device:	GMDN code:	Included Components:
P02.00026/27	IVD CAPSULE PSP WB/SE	62553	abioMIX reagent, pipette, capsule
P02.00024/25	IVD CAPSULE Ferritin WB/SE	58769	abioMIX reagent, pipette, capsule
P02.00022	IVD CAPSULE Aeroallergens	60380	abioMIX reagent, pipette, capsule
P02.00047	IVD CAPSULE COVID-19-SS	64829	abioMIX reagent, capsule; swab
P02.00048	IVD CAPSULE COVID-19-NP	64829	abioMIX reagent, capsule; swab
P02.00045	abioSCOPE Control	N/A	Control capsule
P02.00040	IVD CAPSULE Control PSP	N/A	Control material
P02.00050	IVD CAPSULE D-Dimer	61389	abioMIX reagent, pipette, capsule