The undersigned Leandro Taliani, on behalf of STARK SARL, having a right delegation from the Manufacturer or the Agent for data entry of the medical devices listed below, validation on 10/11/2020 the following information:

System Progressive:	2029679
IVD type:	Reagents, reactive products, kits, control material, calibrators
Trade name and model:	STARK PORTABLE COVID-19 ANTIGEN LAB
Code attributed by the manufacturer (catalog identifier):	COV2PC19AL
Contents of the sales package:	LABORATORY CONSUMABLES (CUVETTE, MICROPROVETTE, SYRINGE, CYTOBRUSH, REAGENTS TO PERFORM THE TEST)
Role of the declarant with respect to the IVD:	MANUFACTURER
Manufacturer:	STARK SARL
The device is new pursuant to article 10, paragraph 4, of Legislative Decree no. 332/2000:	NO
CND classification:	W0105099099 - VIROLOGY - RAPID TESTS AND "POINT OF CARE" – OTHERS
Nomenclature GMDN:	64756 - A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of immunoglobulin G (IgG) and immunoglobulin M (IgM) antibodies to severe acute respiratory syndrome-associated coronavirus 2 (SARS-CoV-2) in a clinical specimen within a short period, relative to standard laboratory testing procedures, using an immunochromatographic test (ICT) method. This test is commonly used in the laboratory or in point-of-care analyses to aid the diagnosis of coronavirus disease (COVID-19) infection. It is not intended to be used for self-testing.
EDMA classification:	15048019 – Coronavirus
CE classification:	Other type of IVD
Annexes according to which the device has been marked:	Annex III
Compliance with common technical specifications:	YES
File containing the EC Declaration of Conformity:	CE Declaration.pdf
Are other devices required for operation:	NO
List of devices (DM/IVD) necessary for operation for exclusive use:	Not present

Technical data

General Technical Characteristics

Intended use pursuant to Legislative Decree 332/2000:	The Stark Portable COVID-19 Portable Lab is an analytical kit to aid in the diagnosis of Covid-19 infection.
Sterile or other special microbiological state of the device (where applicable):	Not present
Special disposal conditions:	According to current regulations

Specific technical data for reagents, reactive products, kits, control materials, calibrators

Method:	It is a non-invasive quantitative analytical immunoassay performed with the ELISA technique with a chemocolorimetric result. The result of the analyzes must be confirmed by other means.
Presence of calibrators:	NO
Positive Controls:	NO
Storage conditions:	between 2 °C and 30 °C
Shelf life of the unopened package (expressed in number of months):	6
Shelf life after first opening of the primary container (expressed in number of days):	0
No. of tests that can be performed [Alternatively, the quantity of reagent and the quantity of single determination reagent (volume / mass)]:	1
Disposable:	YES
No. of units contained in the sales package:	1
List of tissues of human origin or substances derived from them:	Not present
List of biological tissues or substances of animal origin (non-viable):	Not present

Attached documentation

Label	File name: Label Sample COV 2.pdf
Instructions for Use	File name: IFU PORTABLE COVID-19 ANTIGEN LAB.pdf
IVD image Filename:	Cov2 Active Infection Image.pdf

The undersigned declares to be aware of the sanctions provided for in case of false or misleading declarations (Article 76 of the Consolidated Law, D.P.R. 28.12.2000, n. 445).