	<u>CE MARKING - EC DECLARATION OF CONFORMITY</u>	Doc. CQR001-29
Mod. MCR001-1	Device for self-testing listed in annex II	Pag. 1 of 2

for in vitro diagnostic medical devices covered by Directive 98/79/EC:

Classification of the device(s):

- device of list A annex II
- device of list B annex II
- device for self-testing not listed in annex II
- device for self-testing listed in annex II
- other device (all devices except annex II and self-testing devices)

1) We, **PRIMA Lab SA**, declare that the below mentioned device are manufactured by **PRIMA Lab SA**, located in **Via Antonio Monti, 7 – CH 6828 Balerna- Switzerland**.

PRIMA Lab SA is exclusively responsible for this CE marking declaration of conformity.

2) This device complies with all the applicable Essential Principles and Requirements for Safety and Performance of the IVD European Directive 98/79/CE.

3) This compliance has been properly documented according to the following conformity assessment procedure:

- Annex III excluding part 6
- Annex III including part 6
- Annex IV excluding section 4 and 6
- Annex V
- Annex VII
- Examination by a notified body
 - **Name:** mdc medical device certification GmbH
 - **Identification number:** 0483
 - **Address:** Kriegerstrasse, 6 – 70191 Stuttgart, Germany
 - **Certificate n°:** *D1408400052*
 - **Valid until:** 2025-05-26

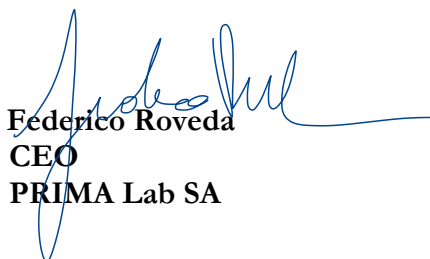
4) **European Representative:**


Name: Qarad EC-REP BV

Address: PAS 257, 2440, Geel - Belgium

5) **Expiry date:** May 26th, 2025

Balerna, May 25th, 2022


Federico Roveda
CEO
PRIMA Lab SA

	<u>CE MARKING - EC DECLARATION OF CONFORMITY</u>	Doc. CQR001-29
Mod. MCR001-1	Device for self-testing listed in annex II	Pag. 2 of 2

Attachment of the EC Declaration of Conformity (the x in the REF is a placeholder and shall indicate the number of tests included in the test kit):

Category	Product and variants	Ref.
<i>Immunochromatographic rapid self-testing devices for the detection of prostate specific antigen PSA</i>	Prostate PSA Test	800080-x
	MyTest Prostate, MyTest Prostaat	380080
	Profar Test PSA	801080
	EASY CARD® PSA SELF TEST	870080-x
	berkeleyhealth Prostate PSA	890080-x
<i>Self-testing system device for the detection of blood glucose</i>	Avanti Blood Glucose Meter / Medidor de Glucosa en Sangre	PL700
	Avanti Blood Glucose Test Strips / Tiras de Prueba de Glucosa en Sangre	PL701
	Avanti Blood Glucose Control Solution / Solución de control de glucosa	PL705

