	CE MARKING - EC DECLARATION OF CONFORMITY SUPPLEMENT	Doc. Supplement to CQR002-34
	Device for self-testing not listed in annex II	Pag. 1 of 2

Supplement to the EC Declaration of Conformity for in vitro diagnostic medical devices covered by Directive 98/79/EC.

This supplement is issued according to Article 110(3) of Regulation (EU) 2017/746 and the relative MDCG 2022-6 “Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR”

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 devices 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 +Supplement D1408400054 +Supplement D1408400059 + Supplement D1408400061 +Supplement D1408400063 +Supplement D1408400064+ Supplement D1408400065
 - **Valid until:** 2025-05-26

4) **European Representative:**

Name: QARAD EC-REP BV

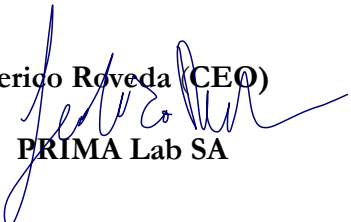
Address: PAS 257 2440 Geel Belgium


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

Balerna, July 27th, 2023

Federico Roveda (CEO)

PRIMA Lab SA



	CE MARKING - EC DECLARATION OF CONFORMITY SUPPLEMENT	Doc. Supplement to CQR002-34
	Device for self-testing not 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.
Immunochromatographic rapid self testing devices for celiac disease screening	Self test Celiachia, diagnosti.care® PARI TestDirect ZÖLIAKIE	1500077-x 124G0040
Immunochromatographic self testing devices for the detection of Group A beta-hemolytic streptococcus bacteria in throat infection	Self test Streptococco A, diagnosti.care®	850060-x
	<i>Newfoundland Strep A Self-test</i>	<i>880060-x</i>
Immunochromatographic rapid self testing devices for early detection of human chorionic gonadotropin hCG in urine	activeMED Schwangerschaftstest	730483
Immunochromatographic rapid self testing devices for the detection of total IgE	PARI TestDirect ALLERGIE IgE	124G0060
Immunochromatographic rapid self testing devices for the detection of Ferritin level in blood	PARI TestDirect EISENMANGEL	124G0050
Colorimetric rapid self-testing device for the semi-quantitative detection of Vitamin D in human whole blood	PARI TestDirect VITAMIN D	124G0030
Urine dipstick devices for self-testing for urinary tract infections	VagiVital® Urinary Tract infection self test	110058-x
Immunochromatographic rapid Self testing devices for the detection of possibly leakage of amniotic fluid	One+Step Amniocheck	500088-x

