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

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**
	Newfoundland Strep A Self-test	***880060-x***
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**