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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 26<sup>th</sup>, 2025

Balerna, May 25<sup>th</sup>, 2022


  
**Federico Roveda**  
**CEO**  
**PRIMA Lab SA**

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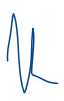
Attachment of the EC Declaration of Conformity (the x in the REF is a placeholder and shall indicate the number of tests included in the test kit):


<b>Category</b>	<b>Product and variants</b>	<b>Ref.</b>
Immunochemical rapid self testing devices for the detection of human chorionic gonadotropin hCG	<b>Pregnancy hCG Test</b> <b>HIGHMED Technology- Pregnancy Test</b> <b>Pharmadoc- Pregnancy Test</b> <b>DoctPharma Pregnancy Test</b> <b>Setablu Pregnancy Test</b> <b>GSV Pregnancy Test</b> <b>SUNLUX® Diagnostic - TEST DI</b> <b>GRAVIDANZA</b>	<b>800030-x;820030-x</b>  <b>805030</b> <b>815030</b> <b>835030-x</b> <b>845030-x</b> <b>855030-x</b> <b>865030-x</b>
Immunochemical rapid self testing devices for the detection of luteinizing hormone LH	<b>Ovulation LH Test</b> <b>Test di Ovulazione Securtest®</b> <b>Safe&amp;Easy Ovulationstest</b>  <b>DeoDoc Ovulation Test</b> <b>EASY CARD® OVULATION SELF TEST</b>  <b>berkeleyhealth Ovulation LH</b>	<b>800050-x;820050-x</b>  <b>801050;821050</b>  <b>803150-x;823150-x</b>  <b>910050-x</b>  <b>870050-x</b>  <b>890050-x</b>
Immunochemical rapid self testing devices for the detection of blood in faeces	<b>Bowel FOB Test</b> <b>MyTest Intestinal</b> <b>Profar Test Colon Retto</b>  <b>EASY CARD® FOB SELF TEST</b>  <b>berkeleyhealth Bowel FOB</b>	<b>800040-x</b> <b>380040</b> <b>801040</b>  <b>870040-x</b>  <b>890040-x</b>
Immunochemical rapid self testing devices for the detection of follicle stimulating hormone FSH	<b>Menopause FSH Test</b>  <b>MyTest Ménopause; MyTest Menopause; Estromineral MyTest-Menopausa</b>  <b>DeoDoc Menopause test</b> <b>EASY CARD® MENOPAUSE SELF TEST</b>  <b>berkeleyhealth Menopause FSH</b>	<b>800011-x</b> <b>820011-x</b>  <b>380011;382011</b>  <b>910011-x</b>  <b>870011-x</b>  <b>890011-x</b>
Immunochemical rapid self -testing devices for the detection of antibodies against Helicobacter pylori	<b>Helicobacter pylori Test</b> <b>MyTest H.pylori-Estomac; MyTest Magen-Vorsorge (H.pylori)</b>  <b>berkeleyhealth Helicobacter pylori</b>	<b>800017-x</b> <b>380017</b>  <b>890017-x</b>



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Immunochematographic rapid self testing devices for the detection of total IgE	<b>Allergy IgE Test</b> <b>MyTest Allergie; MyTest Allergi; MyTest Allergia</b>  <b>EASY CARD® ALLERGY SELF TEST</b>  <b>berkeleyhealth Allergy IgE</b>	800018-x 380018  870018-x  890018-x
Immunochematographic rapid self testing devices for the detection of TSH level in blood	<b>Thyroid TSH Test</b> <b>MyTest Thyroide</b> <b>TEST AUTODIAGNOSTICO TSH</b>  <b>EASY CARD® TSH SELF TEST</b>  <b>berkeleyhealth Thyroid TSH</b>	800021-x 380021 801021  870021-x  890021-x
Immunochematographic rapid self testing devices for the detection of Ferritin level in blood	<b>Iron Fer Test</b> <b>MyTest Jern; MyTest-Ferro; MyTest Eisenmangel; MyTest FerriCheck</b> <b>Test Autodiagnostico Ferro</b>  <b>CASC Eisen Schnelltest</b>  <b>EASY CARD® FERRITIN SELF TEST</b>  <b>berkeleyhealth Iron FER</b>	800025-x 380025  802025 801025-x  805025-x  870025-x  890025-x
Immunochematographic rapid self testing devices for urinary albumin	<b>Kidneys Albumin Test</b> <b>MyTest Albumine</b>  <b>EASY CARD® ALBUMIN SELF TEST</b>  <b>berkeleyhealth Kidney Albumin</b>	800027-x;820027-x 380027;382027  870027-x  890027-x
Immunochematographic rapid self testing devices for the assessment of tetanus protection	<b>Tetanus Test</b> <b>MyTest Tétanos</b>  <b>EASY CARD® TETANUS SELF TEST</b>  <b>berkeleyhealth Tetanus</b>	800092-x 380092  870092-x  890092-x



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Urine dipstick devices for self-testing for urinary tract infections	<b>Urinary Tract Infections Test</b>  <b>MyTest Infection Urinaire, MyTest Harnwegsinfekt, MyTest Urineweg-infectie</b>  <b>Vidi Pharma Selvtest Urinveisinfeksjon</b>  <b>DeoDoc Urinary Tract infection test</b>  <b>EASY CARD® URINARY TRACT INFECTIONS SELF TEST</b>  <b>berkeleyhealth Urinary Tract Infection</b>	<b>100058-x</b>  <b>300058</b>  <b>102058-x</b>  <b>910058-x</b>  <b>170058-x</b>  <b>190058-x</b>
Dry-Chemistry rapid self-testing devices for total cholesterol level detection	<b>Cholesterol Test</b> <b>MyTest Cholestérol; MyTest Cholesterol Armolipid MyTest – Colesterolo; MyTest Cholesterin COLLIPID</b>	<b>100049-x</b> <b>300049</b>  <b>400049</b>
Immunochromatographic rapid self testing devices for the detection of possibly leakage of amniotic fluid	<b>AMNIOCHECK</b> <b>AMNIOSENSE</b> <b>SAUGELLA AmnioCheck</b> <b>AMNIOS</b> <b>AMNIODETECT</b> <b>AL-SENSE</b>  <b>Barza AmnioTest</b>  <b>berkeleyhealth Amniotic Fluid</b>	<b>100088-5;100088-x</b> <b>100088-10</b> <b>300088</b> <b>600088</b> <b>700088</b> <b>900088-2</b> <b>900088-50</b> <b>710088</b>  <b>190088-x</b>
Immunochromatographic rapid self testing devices for celiac disease screening	<b>Celiac Test</b> <b>MyTest Maladie coeliaque, MyTest Glutenintoleranz, MyTest Celiachia Test Autodiagnostico Celiachia</b>  <b>EASY CARD® CELIAC SELF TEST</b>  <b>berkeleyhealth Celiac</b>	<b>100077-x</b> <b>300077</b>  <b>101177-x</b>  <b>170077-x</b>  <b>190077-x</b>
Colorimetric rapid self-testing devices for semi-quantitative determination of pH in female vaginal swab specimens	<b>Vaginal pH Test</b>  <b>DeoDoc Vaginal pH Test</b>  <b>EASY CARD® VAGINAL pH SELF TEST</b>  <b>berkeleyhealth Vaginal pH</b>	<b>100013-x</b>  <b>910013-x</b>  <b>170013-x</b>  <b>190013-x</b>
Colorimetric rapid self-testing devices for in vitro qualitative estimation of sperm concentration in human semen	<b>Sperm Test</b>  <b>DeoDoc Sperm Test</b>  <b>EASY CARD® SPERM SELF TEST</b>  <b>berkeleyhealth Sperm count</b>	<b>100082-x</b>  <b>910082-x</b>  <b>170082-x</b>  <b>190082-x</b>



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Colorimetric rapid self-testing device for the semi-quantitative detection of Vitamin D in human whole blood	<b>Vitamin D Test</b> <b>Test Autodiagnostico Vitamina D</b>  <b>CASC VITAMIN D TEST</b>  <b>EASY CARD® VITAMIN D SELF TEST</b>  <b>berkeleyhealth Vitamin D</b>	<b>100066-x</b> <b>101166-x</b>  <b>105066-x</b>  <b>170066-x</b>  <b>190066-x</b>
Immunochromatographic rapid self testing devices for the detection of specific IgE anti House Dust Mite	<b>ExAller® Dust Mite Allergy Self-Test</b>  <b>House Dust Mite Allergy Self-Test</b>  <b>EASY CARD® DUST MITE ALLERGY SELF TEST</b>	<b>800015</b>  <b>880015-x</b>  <b>870015-x</b>
Immunochromatographic rapid self testing devices for H. pylori detection in stools	<b>Helicobacter pylori Antigen Test</b> <b>TEST AUTODIAGNOSTICO</b> <b>HELICOBACTER PYLORI</b>  <b>EASY CARD® HELICOBACTER SELF TEST</b>  <b>berkeleyhealth Helicobacter pylori antigen</b>	<b>800016-x</b> <b>801016</b>  <b>870016-x</b>  <b>890016-x</b>



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Immunochromatographic rapid self testing devices for the early detection of hCG in urine	<b>Early Pregnancy Test</b>	800010-x
	<b>Early Pregnancy Test</b>	820010-x
	<b>Early Pregnancy Test</b>	825010-x
	<b>LA NUOVA PHARMACIA Early Pregnancy Test</b>	855010-x
	<b>MD MEDICAL Early Pregnancy Test</b>	815110-x
	<b>MEGAPLAST Early Pregnancy Test</b>	815210-x
	<b>PRONTOMED Early Pregnancy Test</b>	815310-x
	<b>MEDIPRO DESPAR Early Pregnancy Test</b>	815410-x
	<b>PAMPHARMA Early Pregnancy Test</b>	815510-x
	<b>PRIMIA Early Pregnancy Test</b>	815610-x
	<b>FORSE SI-FORSE NO Early Pregnancy Test</b>	815710-x
	<b>PiùME MEDICAL Early Pregnancy Test</b>	845010-x
	<b>DERMOPLAST Early Pregnancy Test</b>	815810-x
	<b>CONFIDERM Early Pregnancy Test</b>	815910-x
	<b>ESSERE BENESSERE Early Pregnancy Test</b>	825110-x
	<b>IPER LA GRANDE I Early Pregnancy Test</b>	825210-x
	<b>SELEX Early Pregnancy Test</b>	825310-x
	<b>DIAGNOSTIC TEST Early Pregnancy Test</b>	825410-x
	<b>SICURA Early Pregnancy Test</b>	825510-x
	<b>PARAFARMACIA CONAD Early Pregnancy Test</b>	825610-x
<b>COOP Early Pregnancy Test</b>	825710-x	
<b>U CONFORTA &amp; RISPARMIA Early Pregnancy Test</b>	825810-x	
<b>CONSILIA SAPER SCEGLIERE Early Pregnancy Test</b>	825910-x	
<b>CARREFOUR Early Pregnancy Test</b>	835110-x	
<b>FARMA Early Pregnancy Test</b>	835210-x	
<b>BENNET Early Pregnancy Test</b>	835310-x	
<b>I MEDICALI Early Pregnancy Test</b>	835410-x	
<b>PHARMA Early Pregnancy Test</b>	835510-x	
<b>LLOYDSPHARMACY Early Pregnancy Test</b>	835610-x	
<b>Sanavita Test di Gravidanza</b>	823010-x	
<b>FirstPraedict® CARE FOR YOU®</b>	826010-x	
<b>EASY CARD® PREGNANCY SELF TEST</b>	870010-x	
<b>DeoDoc Early Pregnancy Test</b>	910010-x	
<b>berkeleyhealth Early Pregnancy</b>	890010-x	
Immunochromatographic self testing devices for the detection of Group A beta-hemolytic streptococcus bacteria in throat infection	<b>STREP A TEST</b>	800060-x
	<b>PROFAR STREP A TEST</b>	801060-x
	<b>EASY CARD® STREP A SELF TEST</b>	870060-x
	<b>berkeleyhealth Strep A</b>	890060-x



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Immunochromatographic rapid self-testing device for C-reactive protein levels in blood	<b>C-Reactive Protein Test CRP Test  EASY CARD® CRP SELF TEST  berkeleyhealth C-Reactive Protein</b>	800034-x 880034-x  870034-x  890034-x
self testing device system for the detection of cholesterol in whole blood	<b>Avanti Lipid Panel Meter / Medidor de Perfil de Lípidos  Avanti Cholesterol Test Devices 3-in-1 Lipid Panel / Dispositivos de Prueba Panel de Lípidos 3 en 1  Avanti Cholesterol Test Devices CHOL Total Cholesterol / Dispositivos de Prueba CHOL Colesterol Total  Cholesterol Test Devices TRIG Triglycerides / Dispositivos de prueba TRIG Trigliceridos  Cholesterol Control Devices / Dispositivos de Control de Colesterol Total  Cholesterol Control Solution / Solución de Control de Colesterol  Capillary Transfer Tubes (10µL) / Tubos de Transferencia Capilar Capillary Transfer Tubes (35 µL) / Tubos de Transferencia Capilar</b>	<b>PL600  PL601  PL602  PL603  PL604  PL605  PL606 PL607</b>
self testing device system for the detection of cholesterol in whole blood	<b>Avanti Ultra Cholesterol Monitoring System / Sistema de Monitoreo de Colesterol Avanti Ultra Total Cholesterol Test strips / Tiras de prueba de Colesterol Total  Cholesterol Control Solution / Solución de Control de Colesterol</b>	<b>PL800  PL801  PL805</b>



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Immunochromatographic self testing devices for the detection of SARS-CoV-2 specific antibodies in human capillary blood	<b>COVID-19 Serological Test</b> <b>Serological Self Test COVID</b> <b>COVID-19 Antibody Self Test</b> <b>COVID-19 IgG Spike Self-Test</b> <b>COVID-19 Neutralizing IgG Serological Test</b> <b>Post Vaccine Test</b>  <b>EASY CARD® COVID-19 S-1 SEROLOGICAL SELF TEST</b>  <b>EASY CARD® COVID-19 NC SEROLOGICAL SELF TEST</b>  <b>COVID-19 IgG Self-Test</b>  <b>PRIMACOVID IgG Serological Test</b>	800061-x 800161-x 800261-x 800065-x 800165-x 800265-x  870165-x  870061-x  800069-x  800169-x
Immunochromatographic rapid self-testing devices for the detection of SARS-CoV-2 antigen in oral fluid specimens	<b>COVID-19 Oral Fluid Self-Test</b> <b>COVID-19 Antigen Self-Test (Oral Fluid)</b> <b>COVID-19 Oral Fluid Antigen Test</b> <b>COVID-19 Saliva Self-Test</b>  <b>EASY CARD® COVID-19 SALIVA SELF TEST</b>	100071-x 100171-x 100271-x 100371-x  170371-x
Immunochromatographic self-testing device for the detection of SARS-CoV-2 antigens in human nasal specimens	<b>COVID-19 Antigen Self-Test</b> <b>COVID-19 Self-Test</b> <b>SARS-CoV-2 Antigen Self-Test</b> <b>COVID-19 Nasal Self-Test</b>  <b>PRIMACOVID COVID-19 Self-Test</b>  <b>PRIMACOVID COVID-19 Nasal Self-Test</b>  <b>EASY CARD® COVID-19 ANTIGEN SELF TEST</b>	200063-x 210063-x 220063-x 230063-x  900163-x  900063-x  970063-x

