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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 26th, 2025

Balerna, May 25th, 2022



Federico Roveda
CEO
PRIMA Lab SA

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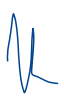
Attachment of the EC Declaration of Conformity (the x in the REF is a placeholder and shall indicate the number of tests included in the test kit):


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



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



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



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



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



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Immunochromatographic rapid self-testing device for C-reactive protein levels in blood	C-Reactive Protein Test CRP Test EASY CARD® CRP SELF TEST berkeleyhealth C-Reactive Protein	800034-x 880034-x 870034-x 890034-x
self testing device system for the detection of cholesterol in whole blood	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	PL600 PL601 PL602 PL603 PL604 PL605 PL606 PL607
self testing device system for the detection of cholesterol in whole blood	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	PL800 PL801 PL805

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Immunochromatographic self testing devices for the detection of SARS-CoV-2 specific antibodies in human capillary blood	COVID-19 Serological Test Serological Self Test COVID COVID-19 Antibody Self Test COVID-19 IgG Spike Self-Test COVID-19 Neutralizing IgG Serological Test Post Vaccine Test EASY CARD® COVID-19 S-1 SEROLOGICAL SELF TEST EASY CARD® COVID-19 NC SEROLOGICAL SELF TEST COVID-19 IgG Self-Test PRIMACOVID IgG Serological Test	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	COVID-19 Oral Fluid Self-Test COVID-19 Antigen Self-Test (Oral Fluid) COVID-19 Oral Fluid Antigen Test COVID-19 Saliva Self-Test EASY CARD® COVID-19 SALIVA SELF TEST	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	COVID-19 Antigen Self-Test COVID-19 Self-Test SARS-CoV-2 Antigen Self-Test COVID-19 Nasal Self-Test PRIMACOVID COVID-19 Self-Test PRIMACOVID COVID-19 Nasal Self-Test EASY CARD® COVID-19 ANTIGEN SELF TEST	200063-x 210063-x 220063-x 230063-x 900163-x 900063-x 970063-x

