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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.

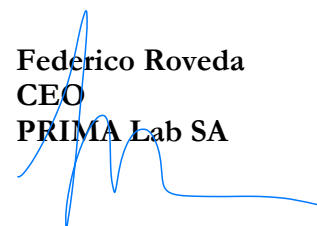
3) This compliance has been properly documented according to the following conformity assessment procedure:


- 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°:** ***D 1408400027***
 - **Valid until:** 2021-01-18

4) Expiry date: January 18th, 2021

Balerna, *October, 28th 2020*

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.
<i>Immunochromatographic rapid self testing devices for the detection of human chorionic gonadotropin hCG</i>	Pregnancy hCG Test HIGHMED Technology- Pregnancy Test Pharmadoct- Pregnancy Test DoctPharma Pregnancy Test	800030-x 805030 815030 835030-x
<i>Immunochromatographic rapid self testing devices for the detection of luteinizing hormone LH</i>	Ovulation LH Test Test di Ovulazione Securtest®	800050-x 801050
<i>Immunochromatographic rapid self testing devices for the detection of blood in faeces</i>	Bowel FOB Test MyTest Intestinal Profar Test Colon Retto	800040-x 380040 801040
<i>Immunochromatographic rapid self testing devices for the detection of follicle stimulating hormone FSH</i>	Menopause FSH Test MyTest Ménopause; MyTest Menopause; Estromineral MyTest-Menopausa	800011-x 380011
<i>Immunochromatographic rapid self-testing devices for the detection of antibodies against Helicobacter pylori</i>	Helicobacter pylori Test MyTest H.pylori-Estomac; MyTest Magen-Vorsorge (H.pylori)	800017-x 380017
<i>Immunochromatographic rapid self testing devices for the detection of total IgE</i>	Allergy IgE Test MyTest Allergie; MyTest Allergi; MyTest Allergia	800018-x 380018
<i>Immunochromatographic rapid self testing devices for the detection of TSH level in blood</i>	Thyroid TSH Test MyTest Thyroïde TEST AUTODIAGNOSTICO TSH	800021-x 380021 801021
<i>Immunochromatographic rapid self testing devices for the detection of Ferritin level in blood</i>	Iron Fer Test MyTest Jern; MyTest-Ferro; MyTest Eisenmangel; MyTest Fer FerriCheck <i>Test Autodiagnostico Ferro</i>	800025-x 380025 802025 <i>801025-x</i>
<i>Immunochromatographic rapid self testing devices for urinary albumin</i>	Kidneys Albumin Test MyTest Albumine	800027-x 380027
<i>Immunochromatographic rapid self testing devices for the assessment of tetanus protection</i>	Tetanus Test MyTest Tétanos	800092-x 380092
<i>Urine dipstick devices for self-testing for urinary tract infections</i>	Urinary Tract Infections Test MyTest Infection Urinaire, MyTest Harnwegsinfekt, MyTest Urineweg-infectie	100058-x 300058
<i>Dry-Chemistry rapid self-testing devices for total cholesterol level detection</i>	Cholesterol Test MyTest Cholestérol; MyTest Cholesterol Armolipid MyTest – Colesterolo; MyTest Cholesterin COLLIPID	100049-x 300049 400049



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<i>Immunochromatographic rapid self testing devices for the detection of possibly leakage of amniotic fluid</i>	AMNIOCHECK AMNIOSENSE SAUGELLA AmnioCheck AMNIOS AMNIODETECT AL-SENSE Barza AmnioTest	100088-5;100088-x 100088-10 300088 600088 700088 900088-2 900088-50 710088
<i>Immunochromatographic rapid self testing devices for celiac disease screening</i>	Celiac Test MyTest Maladie coeliaque, MyTest Glutenintoleranz, MyTest Celiachia <i>Test Autodiagnostico Celiachia</i>	100077-x 300077 <i>101177-x</i>
<i>Colorimetric rapid self-testing devices for semi-quantitative determination of pH in female vaginal swab specimens</i>	Vaginal pH Test	100013-x
<i>Colorimetric rapid self-testing devices for in vitro qualitative estimation of sperm concentration in human semen</i>	Sperm Test	100082-x
<i>Colorimetric rapid self-testing device for the semi-quantitative detection of Vitamin D in human whole blood</i>	Vitamin D Test <i>Test Autodiagnostico Vitamina D</i>	100066-x <i>101166-x</i>
<i>Immunochromatographic rapid self testing devices for the detection of specific IgE anti House Dust Mite</i>	ExAller® Dust Mite Allergy Self-Test	800015
<i>Immunochromatographic rapid self testing devices for H. pylori detection in stools</i>	Helicobacter pylori Antigen Test TEST AUTODIAGNOSTICO HELICOBACTER PYLORI	800016-x 801016



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<i>Immunochromatographic rapid self testing devices for the early detection of hCG in urine</i>	Early Pregnancy Test	800010-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	
<i>Immunochromatographic self testing devices for the detection of Group A beta-hemolytic streptococcus bacteria in throat infection</i>	STREP A TEST	800060-x
<i>Immunochromatographic rapid self-testing device for C-reactive protein levels in blood</i>	PROFAR STREP A TEST	801060-x
<i>Immunochromatographic rapid self-testing device for C-reactive protein levels in blood</i>	C-Reactive Protein Test	800034-x



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<i>self testing device system for the detection of cholesterol in whole blood</i>	Avanti Lipid Panel Meter / Medidor de Perfil de Lípidos	PL600
	Avanti Cholesterol Test Devices 3-in-1 Lipid Panel / Dispositivos de Prueba Panel de Lípidos 3 en 1	PL601
	Avanti Cholesterol Test Devices CHOL Total Cholesterol / Dispositivos de Prueba CHOL Colesterol Total	PL602
	Cholesterol Test Devices TRIG Triglycerides / Dispositivos de prueba TRIG Trigliceridos	PL603
	Cholesterol Control Devices / Dispositivos de Control de Colesterol Total	PL604
	Cholesterol Control Solution / Solución de Control de Colesterol	PL605
	Capillary Transfer Tubes (10µL) / Tubos de Transferencia Capilar	PL606
<i>self testing device system for the detection of cholesterol in whole blood</i>	Avanti Ultra Cholesterol Monitoring System / Sistema de Monitoreo de Colesterol	PL800
	Avanti Ultra Total Cholesterol Test strips / Tiras de prueba de Colesterol Total	PL801
	Cholesterol Control Solution / Solución de Control de Colesterol	PL805
<i>Immunochromatographic self testing devices for the detection of SARS-CoV-2 specific antibodies in human capillary blood</i>	<i>COVID-19 Serological Test</i>	<i>800061-x</i>

