BIOMÉRIEUX

MINI VIDAS®

Simply reliable

PIONEERING DIAGNOSTICS

MINI VIDAS®
Simply reliable

With **MINI VIDAS®** your lab can carry out tests simply and quickly, in a self-contained, space-saving unit. Its user-friendly Load & Go concept means your teams can process up to 36 tests an hour. It also offers excellent reliability, with a MBTF (1) of over 1,100 days.

An improved Design for Increased User Comfort

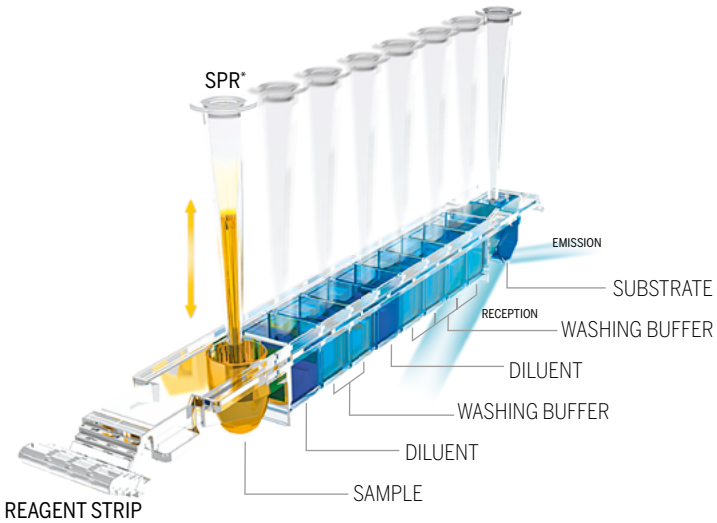
DESIGN

- Streamline your workflow by optimizing test loading
- Increase user-friendliness for data entry and reporting patient results
- Compact solution with integrated computer & printer

11 punktas

RELIABLE

- System robustness (MTBF (1) > 1,100 days)
- Single dose concept, ready-to-use reagents 1 punktas
- Automated barcode identification
- Just Load & Go



FLEXIBLE

- Two independent 6-test sections 5 punktas
- Processing of different parameters simultaneously
- Packaging suite to different test volumes (30 or 60 tests) 7 punktas
- 100 parameters available (2)

	MINI VIDAS®
Weight	40 kg (88 lbs)
Voltage	100-240 VAC
Electric Consumption	1.5-0.8 A
Frequency	50-60 Hz
Power	150 Watts

Discover the VIDAS community and become a member by registering on **www.myvidas.com**

* SPR: Solid Phase Receptacle
(1) MTBF = Mean Time Between Failure
(2) Pending list of assay registered in a specific country

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Assay Solutions

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PIONEERING DIAGNOSTICS

VIDAS® - **PROTOCOLS - UNITS**

VIDAS® - **PARAMETERS**

Protocols VIDAS® / mini VIDAS® / VIDAS 3®

Compatible assays

Parameter Code	Sample volume
TSH	200 µL
T4	200 µL
TSH3	200 µL
FT3	100 µL
FT4N	100 µL
CORS	100 µL
ATPO	100 µL
ATG	100 µL
T3	100 µL
DIG	100 µL
CKMB	250 µL
TNHS	200 µL
TNIU	200 µL
PBN2	200 µL
GAL3	200 µL
PCT	200 µL
MYO	150 µL
DEX2	200 µL

Parameter Code	Sample volume
VWF	100 µL
PC	100 µL
HCG	100 µL
FER	100 µL
IgE	100 µL
AFP	100 µL
E2II	200 µL
AMH (a)	200 µL
PRL	200 µL
LH	200 µL
FSH	200 µL
PRG	200 µL
CEAS	200 µL
199	200 µL
125	200 µL
TPSA	200 µL
FPSA	200 µL
153	100 µL
GDH (a)	300 µL
CDAB (a)	300 µL

Parameter Code	Sample volume
HIV5	200 µL
HIV6	200 µL
P24	200 µL
P24 (a) confirmation test	200 µL
MSG	100 µL
MPG	100 µL
VZG	100 µL
RBM	100 µL
TXC	125 µL
TXGA (b)	2 x 100 µL
TXG	100 µL
TXM	100 µL
RBG	100 µL
B2M	100 µL
CMVG	100 µL
CMVA	2 x 100 µL
HPY	100 µL
CMVM	100 µL
HBCM	100 µL

Parameter Code	Sample volume
HBS	150 µL
AHBS	200 µL
HBS (a) confirmation test	150 µL
HBST	150 µL
HCV	100 µL
HBCT	150 µL
HAVT	150 µL
HBE	150 µL
HBL	150 µL
HBL (a) confirmation test	150 µL
HBET (a)	150 µL
HAVM	100 µL

Parameter Code	Sample volume
LYM	100 µL
LYG	100 µL
LYGS	100 µL
VCAG	100 µL
VCAM	100 µL
EBNA	100 µL
VITD	100 µL
TES2	100 µL

(a) = After sample processing
(b) = After dilution to obtain 15 IU/mL

Units VIDAS® / mini VIDAS® / VIDAS 3®

Only parameters for which results can be expressed in different units are given in this table.

Parameter Code	Proposed VIDAS Unit	Conversion Factors
E2II	pmol/L nmol/L → pg/mL	pg/mL x 3.67 → pmol/L pmol/L x 0.272 → pg/mL
FT4	pg/mL ng/dL ng/L ng/100 mL → pmol/L	pmol/L x 0.777 → pg/mL pg/mL x 1.29 → pmol/L
T4	µg/L µg/100 mL µg/dL → nmol/L	nmol/L x 0.777 → µg/L µg/L x 1.29 → nmol/L
FT3	pg/mL ng/L → pmol/L	pmol/L x 0.651 → pg/mL pg/mL x 1.54 → pmol/L
T3	ng/mL µg/L µg/100 mL µg/dL → nmol/L	nmol/L x 0.651 → µg/L µg/L x 1.54 → nmol/L
FER	µg/L → ng/mL	
CORS	nmol/L µg/dL µg/L → ng/mL	nmol/L x 0.362 → ng/mL ng/mL x 2.76 → nmol/L

Parameter Code	Proposed VIDAS Unit	Conversion Factors
PRL	µUI/mL µIU/mL ng/mL 1 IRP → ng/mL 3 IS	1 ng 1st IRP = 32 µ UI 1 ng 3rd IS = 21 µ UI 1 ng/mL 3rd IS = 1.524 ng/mL 1st IRP
B2M	µg/mL UI/mL IU/mL kUI/L kIU/L → mg/L	mg/L x 14 → UI/mL UI /mL x 0.071 → mg/L
AFP	µg/L ng/mL µg/mL IU/mL → UI/mL	ng/mL x 0.826 → UI/mL UI /mL x 1.21 → ng/mL
TNHS →	ng/L pg/mL	
TNIU	ng/mL → µg/L	
PBN2	pmol/L → pg/mL	
PCT	µg/L → ng/mL	
MYO →	µg/L ng/mL	
VITD →	ng/mL nmol/L	
GAL3	ng/mL	

Parameter Code	Proposed VIDAS Unit	Conversion Factors
CEAS	ng/mL	ng/mL x 15.43 → mUI/mL
AMH** →	ng/mL pmol/L ng/dL	pmol/L x 0.14 → ng/mL ng/mL x 7.14 → pmol/L
FSH LH →	IU/L mIU/mL UI/L mUI/mL	
HAVT	IU/L mIU/mL UI/L → mUI/mL	
HCG	UI/L → mIU/mL IU/L kUI/L kIU/L mUI/mL	
DIG	nmol/L µg/L → ng/mL	nmol/L x 0.781 → ng/mL ng/mL x 1.28 → nmol/L
PRG	nmol/L → ng/mL	nmol/L x 0.3145 → ng/mL ng/mL x 3.1796 → nmol/L
TES2	nmol/L → ng/mL ng/dL	nmol/L x 0.288 → ng/mL ng/mL x 3.47 → nmol/L
IgE	UI/mL kIU/L → IU/mL kUI/L	

Parameter Code	Proposed VIDAS Unit	Conversion Factors
ST →	kIU/L kUI/L	
TSH	mUI/L µIU/mL mIU/L → µUI/mL	
TSH3	µIU/mL → µUI/mL	
HBST AHBS →	mIU/mL mUI/mL	
P24 →	pg/mL Ag P24 pg/mL Ag VIH	1pg/mL of P24 = 3.65 pg/mL
CMVG	AU/mL → UA/mL	
RBG →	UI/mL IU/mL	
TXG	IU/mL → UI/mL	
vWF	UI/mL	
PC	IU/mL → %	
DEX2	µg/mL → ng/mL	(FEU) (FEU)
HBCM	PEIU/mL	

FEU: Fibrinogen Equivalent Unit
→ Default Unit

VIDAS® / mini VIDAS® / VIDAS® 3: Parameters

Range	Parameter	Reference	Code	Sample Volume	Calibration-Control		Sample Pre-Treatment	Test validated using	Test time (minutes)	Measurement Range or Interpretation
					Test	Frequency				
EMERGENCY										
BACTERIAL INFECTION	B.R.A.H.M.S PCT™	30450	PCT	200 µL	S1 S1 S2 S2 C1 C2	28 days	no	Serum, Plasma (Hep.) (2)	20	0.05 - 200 ng/mL
3 punktas	NT-proBNP2	30458	PBN2	200 µL	S1 S1 S2 S2 C1 C2	28 days	no	Serum, Plasma (Hep.)	20	15 - 25,000 pg/mL
	Troponin I Ultra	30448	TNIU	200 µL	S1 S1 S2 S2 C1 C2	28 days	no	Serum, Plasma (Hep.)	20	0.01 - 30 µg/L
CARDIAC	Hs Troponin I (C)	415386	TNHS	200 µl	S1 S1 S2 S2 C1 C2	28 days	no	Serum, Plasma (Hep.)	20	
	Galectin-3	411191	GAL3	200 µL	S1 S1 C1	28 days	no	Serum, Plasma (Hep., EDTA)	20	3.3 - 100 ng/mL
	Myoglobin	30446	MYO	150 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep.)	17	5 - 1,000 µg/L
	CK-MB	30421	CKMB	250 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep., EDTA)	30	0.8 - 300 ng/mL
	Digoxin	30603	DIG	100 µL	S1 S1 S1 C1	14 days	no	Serum, Plasma (Hep., EDTA)	20	0.2 - 5 ng/mL
VENOUS THROMBO-EMBOLISM / COAGULATION	D-Dimer Exclusion™ II	30455	DEX2	200 µL	S1 S1 C1 C2	28 days	no	Plasma (Cit.)	20	45 - 10,000 ng/mL (FEU)
	Protein C	30115	PC	100 µL	S1 S1 C1	14 days	no	Plasma (Cit.)	35	1 - 120 %
	vWF	30436	vWF	100 µL	S1 S1 C1	14 days	no	Plasma (Cit.)	35	1 - 120 %
INFECTIOUS DISEASES										
HEPATITIS	HAV IgM	30307	HAVM	100 µL	S1 S1 C1 C2	14 days	no	Serum, Plasma (EDTA, Hep.)	60	Qualitative test: Negative, Positive or Equivocal
	Anti-HAV Total	30312	HAVT	150 µL	S1 S1 C1 C2	14 days	no	Serum, Plasma (EDTA, Hep., Cit.)	90	15 - 400 mIU/mL
	HBs Ag Ultra (1)	30315	HBS• HBL	150 µL	S1 S1 C1 C2	14 days	no	Serum, Plasma (Hep.)	60 / 90	Qualitative test: Negative or Positive
	Anti-HBsT II	30318	AHBS	200 µL	S1 S1 C1 C2	28 days	yes (2)	Serum, Plasma (Hep.)	60	3 - 500 mIU/mL
	Anti-HBc Total II	30314	HBCT	150 µL	S1 S1 S1 C1 C2	14 days	no	Serum, Plasma (EDTA, Hep., Cit.)	90	Qualitative test: Negative, Positive or Equivocal
	HBc IgM II	30439	HBCM	100 µL	S1 S1 C1 C2	14 days	no	Serum, Plasma (EDTA, Hep., Cit.)	55	0 - 200 PEIU/mL
	HBe Ag	30305	HBE	150 µL	S1 S1 C1 C2	14 days	no	Serum, Plasma (EDTA, Hep., Cit.)	90	Qualitative test: Negative or Positive
	Anti-HCV	30308	HCV	100 µL	S1 S1 C1 C2	28 days	no	Serum, Plasma (Hep.)	40	Qualitative test: Negative or Positive
HIV	HIV DUO Ultra	30443	HIV5	200 µL	S1 S1 S2 S2 C1 C2 C3	14 days	no	Serum, Plasma (EDTA, Hep.) (2)	120	Ag and Ab qualitative test: Negative or Positive
	HIV DUO Quick	30447	HIV6	200 µL	S1 S1 C1 C2 C3	14 days	no	Serum, Plasma (EDTA, Hep.) (2)	80	Qualitative test: Negative or Positive
	HIV P24 II (1)	30117	P24	200 µL	S1 S1 C1 C2	14 days	no	Serum, Plasma (EDTA, Hep., Ox., Thrombin)	90	0 - 400 pg/mL of Ag P24
ToRC	Toxo IgM	30202	TXM	100 µL	S1 S1 C1 C2	14 days	no	Serum (3)	40	Qualitative test: Negative, Positive or Equivocal
	Toxo IgG II	30210	TXG	100 µL	S1 S1 C1 C2	14 days	no	Serum (3), Plasma (EDTA, Hep.)	40	0 - 300 IU/mL
	Toxo Competition	30211	TXC	125 µL	S1 S1 C1 C2	14 days	no	Serum, Plasma (EDTA, Hep.)	40	Qualitative test: Negative or Positive
	Toxo IgG Avidity (4)	30222	TXGA	2 x 100 µL	C1 C2	14 days	no	Serum (3), Plasma (EDTA, Hep., Cit)	40	Avidity index (AI) An AI ≥ 0.3 is a strong indication of a primary infection dating back more than 4 months. An AI < than 0.3 does not enable a recent infection to be differentiated from a former infection.
	Rub IgM	30214	RBM	100 µL	S1 S1 C1 C2	14 days	no	Serum	60	Qualitative test: Negative, Positive or Equivocal
	Rub IgG II	30221	RBG	100 µL	S1 S1 C1 C2	14 days	no	Serum, Plasma (EDTA, Hep.)	40	0 - 400 IU/mL
	CMV IgM	30205	CMVM	100 µL	S1 S1 C1 C2	14 days	no	Serum	60	Qualitative test: Negative, Positive or Equivocal
	CMV IgG	30204	CMVG	100 µL	S1 S1 C1 C2	14 days	no	Serum	40	0 - 400 AU/mL
	CMV IgG Avidity II	413557	CMVA	2 x 100 µL	CH CL	14 days	no	Serum	40	Avidity index (AI) An AI ≥ 0.65 is a strong indication of a primary infection dating back more than 5 months. An AI < than 0.40 is a strong indication of a primary infection dating back less than 3 months. An 0.40 < AI < 0.65 does not enable to distinguish a recent infection from a former infection.
OTHER SEROLOGIES	EBV VCA IgM	30237	VCAM	100 µL	S1 S1 S1 C1 C2	28 days	no	Serum	40	Qualitative test: Negative, Positive or Equivocal
	EBV VCA/EA IgG	30236	VCAG	100 µL	S1 S1 S1 C1 C2	28 days	no	Serum	40	Qualitative test: Negative, Positive or Equivocal
	EBV EBNA IgG	30235	EBNA	100 µL	S1 S1 S1 C1 C2	28 days	no	Serum	40	Qualitative test: Negative, Positive or Equivocal
	Lyme IgM	30319	LYM	100 µL	S1 S1 C1 C2	28 days	no	Serum, Plasma (Hep.)	27	Qualitative test: Negative, Positive or Equivocal
	Lyme IgG	30320	LYG	100 µL	S1 S1 C1 C2	28 days	no	Serum, Plasma (Hep.), /CSF	27	Qualitative test: Negative or Positive
	Measles IgG	30219	MSG	100 µL	S1 S1 C1 C2	14 days	no	Serum	40	Qualitative test: Negative, Positive or Equivocal
	Mumps IgG	30218	MPG	100 µL	S1 S1 C1 C2	14 days	no	Serum	40	Qualitative test: Negative, Positive or Equivocal
	Varicella-Zoster IgG	30217	VZG	100 µL	S1 S1 C1 C2	14 days	no	Serum	40	Qualitative test: Negative, Positive or Equivocal
	H. pylori IgG	30192	HPY	100 µL	S1 S1 C1 C2	14 days	no	Serum, Plasma (EDTA)	40	Qualitative test: Negative, Positive or Equivocal
ANTIGEN DETECTION	*C. difficile* GDH	30125	GDH	300 µL	S1 S1 C1 C2	28 days	yes (2)	Stool	50	Qualitative test: Negative or Positive
	C. difficile Toxin A&B	30118	CDAB	300 µL	S1 S1 C1 C2 C3	14 days	yes (2)	Stool	75	Qualitative test: Negative, Positive or Equivocal
IMMUNOCHEMISTRY										
REPRODUCTION / FERTILITY	AMH (d)	417011	AMH	200 µL	S1 S1 C1	28 days	no	Serum, Plasma (Lith., Hep.)	40	0.02 – 9 ng/mL
	Estradiol II	30431	E2II	200 µL	S1 S1 S1 C1	14 days	no	Serum, Plasma (Hep.)	60	9 - 3,000 pg/mL
	FSH	30407	FSH	200 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep.)	40	0.1 - 110 mIU/mL
	HCG	30405	HCG	100 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep., EDTA)	30	2 - 1,500 mIU/mL
	LH	30406	LH	200 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep.)	40	0.1 - 100 mIU/mL
	Prolactin	30410	PRL	200 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep.)	40	0.5 - 200 ng/mL
	Progesterone	30409	PRG	200 µL	S1 S1 S1 C1	14 days	no	Serum, Plasma (Hep., EDTA, Silicone, Gel)	45	0.25 - 80 ng/mL
	Testosterone II	414320	TES2	100 µl	S1 S1 C1	28 days	no	Serum, Plasma	40	0.05 to 13.50 ng/mL
THYROID	TSH	30400	TSH	200 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep., Beads, Gel)	40	0.05 - 60 µIU/mL
	TSH3	30441	TSH3	200 µL	S1 S1 S2 S2 C1 C2	14 days	no	Serum, Plasma (Hep., Silicone, Gel)	80	0.005 - 100 µIU/mL
	FT3	30402	FT3	100 µL	S1 S1 S1 C1	14 days	no	Serum, Plasma (Hep.)	40	0.7 - 45 pmol/L
	FT4	30459	FT4N	100 µL	S1 S1 C1	14 days	no	serum, plasma (Hep., Silicone, Gel)	40	1 - 100 pmol/mL
	T3	30403	T3	100 µL	S1 S1 S1 C1	14 days	no	Serum, Plasma (Hep.)	40	0.4 - 9 nmol/L
	T4	30404	T4	200 µL	S1 S1 S1 C1	14 days	no	Serum, Plasma (Hep.)	40	6 - 320 nmol/L
	Anti-TPO	30461	ATPO	100 µL	S1 S1 C1	28 days	no	Serum, Plasma (Hep., EDTA, Silicone, Gel)	25	0.8 - 1,000 IU/mL
	Anti-Tg	30462	ATG	100 µL	S1 S1 C1	28 days	no	Serum, Plasma	25	6.4 - 800 IU/mL
TUMOUR MARKERS	AFP	30413	AFP	100 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep., EDTA), Amniotic Fluid	30	0.5 - 400 IU/mL
	CA 15-3*	30429	153	100 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep, EDTA)	60	2 - 400 U/mL
	CA 19-9™	30427	199	200 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep, EDTA)	60	3 - 500 U/mL
	CA 125 II™	30426	125	200 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep, EDTA)	60	4 - 600 U/mL
	CEA S	30453	CEAS	200 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep.)	60	0.5 - 200 ng/mL
	FPSA	30440	FPSA	200 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep., EDTA)	60	0.05 - 10 ng/mL
	TPSA	30428	TPSA	200 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep., EDTA)	60	0.07 - 100 ng/mL
ALLERGY	Total IgE	30419	IgE	100 µL	S1 S1 C1	14 days	no	Serum, Plasma (Lith., Hep., EDTA)	30	0.5 - 1,000 kIU/L
OTHERS	Cortisol S	30451	CORS	100 µL	S1 S1 S1 C1	14 days	yes (urine)	Serum, Plasma (Hep., EDTA), 24-hour Urine	40	2 - 650 ng/mL
	Ferritin	30411	FER	100 µL	S1 S1 C1	14 days	no	Serum, Plasma (Hep., EDTA)	30	1.5 - 1,200 ng/mL
	ß2 Microglobulin	30420	B2M	100 µL	S1 S1 C1 C2	14 days	yes (urine)	Serum, Plasma (Hep., EDTA), Urine	40	0.004 - 4 mg/L
3 punktas	25 OH Vitamin D Total	30463	VITD	100 µL	S1 S1 C1	28 days	no	Serum, Plasma (Lith., Hep.)	40	8.1 - 126 ng/mL

• HBL = long protocol

(c) = Some of these reagents have not yet obtained regulatory clearance in some countries. Please contact your local bioMérieux representative for further information and product availability.
Some references may vary according the country. Please contact your local bioMérieux representative for further information and product availability.
(d) = Not available in the following countries, regions and states: Armenia, Australia, Austria, Azerbaijan, Belarus, Belgium, Canada, Denmark, France, Germany, Hong-Kong, Ireland, Israel, Italy, Japan, Kazakhstan, Kyrgyzstan, Lichtenstein, Moldavia, New Zealand, Portugal, Russia, Spain, Switzerland, Tajikistan, The Netherlands, Turkey, Turkmenistan, United Kingdom.

(1) = Confirmation test available
(2) = See package insert
(3) = Inactivated or not 30 mins at 56°C
(4) = Double strips

Benefit from bioMérieux's experience

with VIDAS® services, ensuring your lab's continued development

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Vertimas iš anglų kalbos

Mielas kliente,

Dėkojame Jums, kad darbui laboratorijoje pasirinkote VIDAS® imunologinių tyrimų sistemą.

Šio laiško tikslas - pateikti Jums bioMerieux rekomendacijas dėl kalibracijos ir kokybės kontrolės atlikimo.

VIDAS® sistema apdoroja mėginius laisvąja kreiptimi partijos režime, naudojant vieno tyrimo formatą (strypelis ir SPR antgalis), remiantis ELFA technologija, visiems analizės tipams: serologiniai, imunocheminiai tyrimai, antigenų nustatymas ir industrinė mikrobiologija.

Kiekvienam parametrui kalibraciją privaloma atlikti atidarius naują rinkinį ir tam, kad kalibracinė kreivė būtų atnaujinta. Pakartotinas kalibravimas turi būti atliekamas kas 14 arba 28 dienas (priklausomai nuo tyrimo, žiūrėkite pakuotės informacinį lapelį).

Rinkinyje esančios kontrolės yra skirtos patvirtinti atliktą kalibraciją. Jas privaloma atlikti pradėjus naudoti naują rinkinį tam, kad būtų patikrinta rinkinio reagentų kokybė.

Laikydamiesi šių rekomendacijų užtikrinsite, kad Jūsų laboratorijos darbas atitinka bioMerieux nurodymus.

Vis dėlto, galite nusistatyti savo kokybės kontrolės atlikimo dažnį pagal savo laboratorijos tvarką, remiantis rinkos analize. Riziką keliančių priežasčių identifikavimui ir jų sprendimui (apmokymas, procedūros, kokybės kontrolės...) bioMerieux rekomenduoja naudoti Ishikawa diagramą.
Šiuo klausimu esame pasiruošę Jums padėti.

Prašome išplatinti šią informaciją visam laboratorijos personalui ir išsaugoti šio laiško kopiją archyvo dokumentuose bei persiųsti šalims, kurioms Jūs galite tiekti šiuos produktus.

Dėkojame, kad pritaikote šias procedūras savo laboratorijoje. Iškilus klausimams arba jeigu Jums reikia pagalbos, kreipkitės į vietinį atstovą.

Mes įsipareigojame Jums tiekti aukščiausios kokybės produktus ir paslaugas.
Dėkojame, kad ir toliau pasitikite bioMerieux kompanija ir jos produktais.

/parašas/
Gabriel Pedone
Rinkodaros vadovas
Imunologinių tyrimų padalinys

/parašas/
Marie-Claude Bernard
Produktų imunologiniams tyrimams vadovas
Atstovai Vidurio Rytuose/Afrikoje/Europoje

Tikslus dokumento vertimas į lietuvių kalbą
Vertėjas (-a) A. Gepelevičienė
Data: 2017-05-08
UAB Diamedica
Molėtų pl. 73, Vilnius
Lietuva
Tel. 8 5 279 0080

BIOMÉRIEUX

Marcy l'Etoile, September 20th, 2013

Dear Customer,

You have chosen the VIDAS® system for your laboratory and we thank you for your confidence.

The aim of this letter is to give you the bioMérieux recommendations regarding calibration and controls.

The VIDAS® system processes samples in random access and batch mode using a single test format (strip and SPR) based on the Enzyme Linked Fluorescent Assay (ELFA) technology for all types of analysis: serology, immunochemistry, antigen detection and industrial microbiology.

For each parameter, a calibration should be done at the opening of the kit and a recalibration every 14 or 28 days (depending on the assay, please refer to package insert) to readjust the calibration curve.

The purpose of the controls included in the kit is to validate calibrations. They should also be run immediately after opening a new kit to ensure that reagent performances have not been altered.

Compliance with these recommendations allows your laboratory to be in line with bioMérieux guidelines.

Nevertheless, you may adapt your quality control frequency according to your laboratory organisation based on a risk analysis. bioMérieux recommends to use the Ishikawa diagram to identify causes likely to present a risk and find the appropriate answer (training, procedures, quality controls ...).
We can help you in this approach.

Please distribute this information to all appropriate personnel in your laboratory, keep a copy in your files, and forward it to other parties to whom you may have transferred our product.

We thank you for applying these procedures in your laboratory. If you have any questions or need assistance, please contact your local bioMérieux representative.

We are committed to providing you with products, support and services of the highest quality.
Thank you for your continued confidence in bioMérieux and our products.

Gabriel Pedone
Global Marketing Manager
ImmunoAssay Unit

Marie-Claude Bernard
Product Manager ImmunoAssays
Middle-East/ Africa/ Europe Distributors

3 Sistemos aprašas ir pagrindinės procedūros

Prietaiso *mini VIDAS*® analizatorius aprašymas

3-1 pav. ***mini VIDAS***® analizatorius

1 – darbinės būsenos lemputė
2 – SPR® blokas
3 – juostelių sekcija
4 – juostelės paruošimo dėklas
5 – klaviatūra ir ekranas
6 – termografinis spausdintuvas
7 – išorinis brūkšninių kodų skaitytuvas

Pastaba. *Ankstesnių versijų prietaise* ***mini VIDAS***® *analizatorius juostelės paruošimo dėklo gali nebūti.*

DĖMESIO! Niekada nenaudokite kitokių medžiagų, nei nurodė bioMérieux.

Vidas

BIOMÉRIEUX

PIONEERING DIAGNOSTICS

THE VIDAS CONCEPT

1 patient, 1 test, 1 result

can be used 24/7, with over 100 references in single test format

Some of these reagents have not yet obtained regulatory clearance in some countries. Please contact your local bioMérieux representative for further information and product availability.
Please refer to your local and/or international guidelines for the use of biomarkers.

Dear Customer,

The world of medicine is changing. Today, its focus has shifted from diagnosing a pathology to assessing what is unique about each patient.

The individual is always at the heart of the VIDAS® approach, yet its strength also lies in its exceptional network of over **25,000 customers**. Together, the VIDAS global teams and network make up an impressive force, ready to embrace the new medical, scientific and economic realities of healthcare today.

The VIDAS Solution will make an essential contribution to meeting the demands of a world where controlling health expenditure has become crucial and where, as a result, diagnostics have taken on critical importance.

Your bioMérieux team

2016
Launch of AMH*

2015
Launch of VIDAS®
High sensitive Troponin I

2014
Launch of C. *Difficile* GDH

2013
New heart failure marker Galectin 3.
Vitamin D is available in single test format on VIDAS.

2007
Launch of VIDAS® Procalcitonin assay, the new reference for the diagnosis of severe bacterial infection/sepsis.

2004
First test cleared by the FDA for an exclusion claim: VIDAS® D-Dimer Exclusion.

2001
New cardiac assay to identify cardiac conditions: Troponin I.

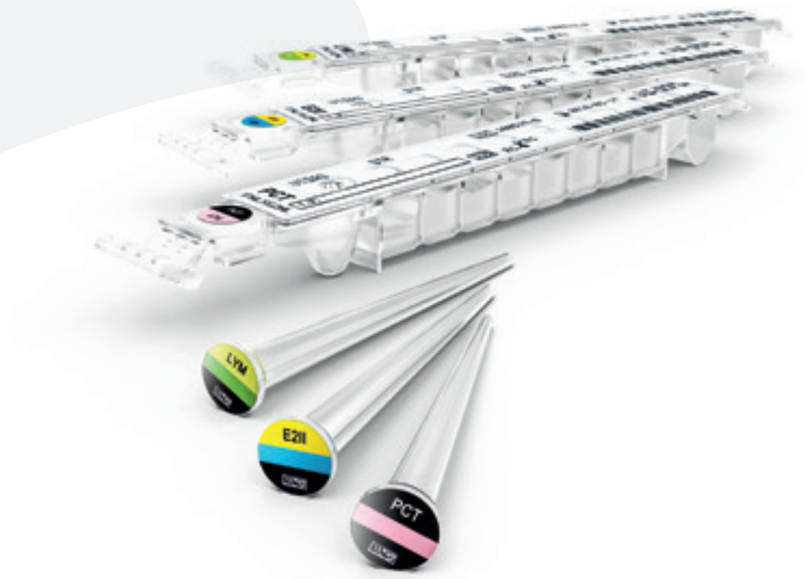
1998
VIDAS® HIV DUO: first 4th advanced generation automated assay.

1995
Launch of VIDAS® D-Dimer, the gold standard assay for Deep Venous Thrombosis and Pulmonary Embolism.

1994
VIDAS® HIV p24 Ag: first quantitative Ag detection assay in automated format.

1993
VIDAS® Toxoplasmosis Avidity: first assay for exclusion of recent toxoplasmosis infection.

* VIDAS® AMH is not available in the following countries, states and regions: Armenia, Australia, Austria, Azerbaijan, Belarus, Belgium, Canada, Denmark, France, Germany, Hong-Kong, Ireland, Israel, Italy, Japan, Kazakhstan, Kyrgyzstan, Liechtenstein, Moldavia, New Zealand, Portugal, Russia, Spain, Switzerland, Tajikistan, The Netherlands, Turkey, Turkmenistan, United Kingdom.



THE SINGLE TEST CONCEPT

The success of VIDAS is based on the robustness and reliability of its reagent design, combined with its ready-to-use single test concept with ELFA* technology.

HOW IT WORKS

The VIDAS principle is based on the interaction of two elements: the coated SPR® (Solid Phase Receptacle), containing antigens or antibodies, and the Strip, made up of a series of wells containing the correct amount of reagent necessary for the test.

CONFIDENCE IN RESULT REPORTING AND COST MANAGEMENT

8_9_10 punktai

High quality VIDAS reagents offer a dynamic measurement range **with proven accuracy and performance**, reducing unnecessary repeat tests.

All types of assays can be run simultaneously **without any risk of contamination** due to absence of external washing solution, drains and syringes for sample or reagent pipetting.

Each parameter has a single reference with reagent, standard, control and diluent included in the kit. Management is simple with minimum operator handling and intervention.

* Enzyme Linked Fluorescent Assay.

THE VIDAS® INSTRUMENTS RANGE

VIDAS instruments are bench-top automated immunoassay systems based on ELFA technology. They offer your laboratory high quality, on demand test results for small volume testing.

All VIDAS instruments are operational 24/7 and use the same reagent references. They allow you to process several different parameters simultaneously, in both single random access sample and batch test mode, for all types of analyses. Their unique design guarantees that there is no inter-reagent or inter-sample contamination.

mini VIDAS

SIMPLY RELIABLE

With mini VIDAS® your lab can carry out tests simply and quickly, in a self-contained, space-saving unit. Its user-friendly Load & Go concept means your teams can process up to 36 tests an hour. It also offers excellent reliability, with a Mean Time Between Failures (MBTF) of over 1,100 days.

VIDAS

THE PIONEER

VIDAS® offers your lab simplicity and productivity, with its loading capacity of 30 tests. It will enhance your workflow, allowing you to handle batch series while maintaining specific management of emergency tests, thanks to its five independent compartments.

VIDAS® also guarantees fast, reliable results, processing up to 80 tests per hour and offering a Mean Time Between Failures (MTBF) of over 700 days.

VIDAS 3

ENHANCED IN-LAB ORGANISATION

The VIDAS 3 system brings maximum peace of mind to your lab. Flexible and fully automated, it enables you to run up to 12 tests in 4 independent sections with complete security, guaranteed traceability and 24/7 access.

VIDAS 3 is designed with:

- Intuitive software,
- Fully automated pipetor action.

VIDAS 3 ensures test security thanks to:

- Complete traceability of all actions,
- Integrated quality control management,
- Bi-directional Laboratory Information System (LIS) connectivity.

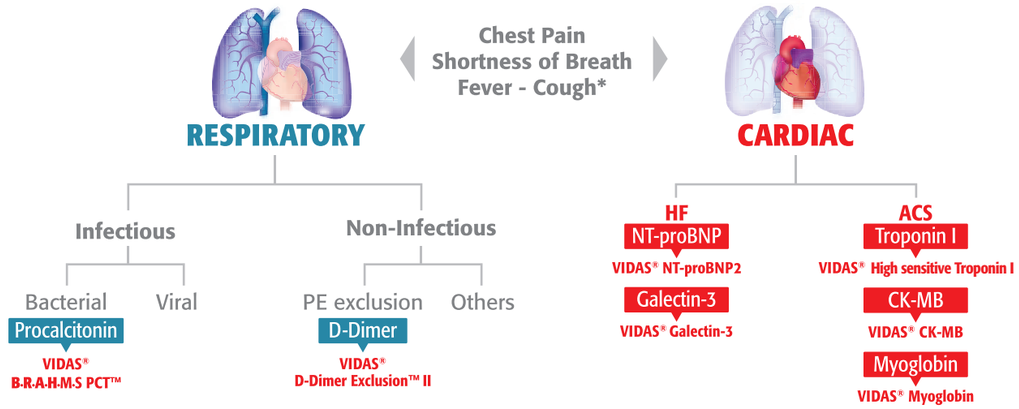
VIDAS 3 is flexible with access at all times:

- Temperature-controlled loading bay, 27 samples, diluents and calibrators in three separate racks,
- 4 independent test compartments of 3 tests each - Up to 36 tests per hour.

ACUTE CARE

High sensitive Troponin I, NT-proBNP, D-Dimer, PCT, a unique test offer on a single device

Efficient and fast patient triage is essential in the Emergency Department, where common symptoms like chest pain, shortness of breath and fever require rapid decisions on hospitalization, investigations and treatment. [1]



* Among the top-10 reasons for visiting an emergency department (National Hospital Ambulatory Medical Care Survey, 2011 Emergency Department Fact Sheet: www.cdc.gov/nchs/ahcd/factsheets.htm).
HF: Heart Failure - ACS: Acute Coronary Syndrome - PE: Pulmonary Embolism

VIDAS® and its unique, comprehensive and user-friendly panel allows you to manage urgent samples separately from routine activity and comply with the short turnaround time required by such complex clinical situations. That means improved patient management and less stress for doctors.

	VIDAS® B.R.A.H.M.S PCT™	VIDAS® D-Dimer Exclusion™ II	VIDAS® High sensitive Troponin I	VIDAS® NT-proBNP2	VIDAS® Galectin-3
Sample type	Plasma (heparin) Serum	Plasma (citrate)	Plasma (heparin) Serum	Plasma (heparin) Serum	Plasma (heparin, EDTA) Serum
Time to result	**20 min** (no warm-up period, load and start)	**20 min** (no warm-up period, load and start)	**20 min** (no warm-up period, load and start)	**20 min** (no warm-up period, load and start)	**20 min** (no warm-up period, load and start)

1. Wiler JL, Gentle C, Halfpenny JM, Heins A, Mehrotra A, Mikhail MG, Fite D. Optimizing emergency department front-end operations. Ann Emerg Med. 2010;55:142-160.e1.

SEPSIS

B.R.A.H.M.S PCT™ Guidance for Antibiotic therapy

When emergency teams suspect severe bacterial infection, sepsis or lower respiratory tract infection (LRTI), early diagnosis is essential.

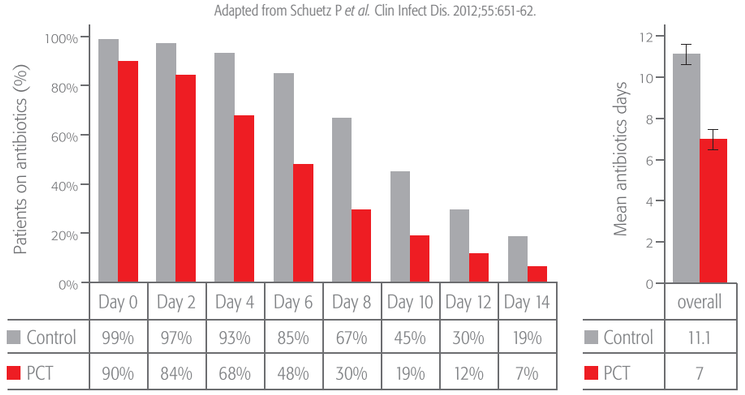
Procalcitonin (PCT) blood levels rise rapidly during bacterial infections. It has been demonstrated that PCT helps to assess the severity of an infection and supports the early recognition of sepsis. [1] Procalcitonin has also been shown to be a valuable decision-support tool for the initiation, continuation or cessation of antibiotic treatment.

The use of PCT to guide antibiotic therapy has been described in various clinical settings. One example is the management of patients with community-acquired pneumonia (CAP) in emergency departments:

-37% Reduction in Antibiotics use

Antibiotic use in CAP patients with (red) and without (grey) PCT guidance.

Adapted from Schuetz P *et al.* Clin Infect Dis. 2012;55:651-62.

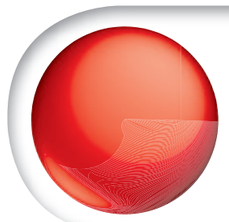


	Day 0	Day 2	Day 4	Day 6	Day 8	Day 10	Day 12	Day 14
Control	99%	97%	93%	85%	67%	45%	30%	19%
PCT	90%	84%	68%	48%	30%	19%	12%	7%

	overall
Control	11.1
PCT	7

With PCT guidance, patients were treated for a mean of 7 days compared to 11.1 days in the control group, indicating a reduction in antibiotic exposure of around 40% (Schuetz *et al.*, 2012 [2]).

1. Bouadma L, Luyt CE, Tubach F *et al.* Use of procalcitonin to reduce patients' exposure to antibiotics in intensive care units (PRORATA trial): a multicentre randomised controlled trial. Lancet 2010;375 (9713 463-74).
2. Schuetz P, Briel M, Christ-Crain M *et al.* Procalcitonin to guide initiation and duration of antibiotic treatment in acute respiratory infections: an individual patient data meta-analysis. Clin Infect Dis. 2012;55:651–662.



ACUTE CARE PANEL

B.R.A.H.M.S PCT™, D-Dimer Exclusion™ II, High sensitive Troponin I, NT-proBNP2, Galectin-3, CK-MB, Myoglobin, Digoxin

CARDIAC

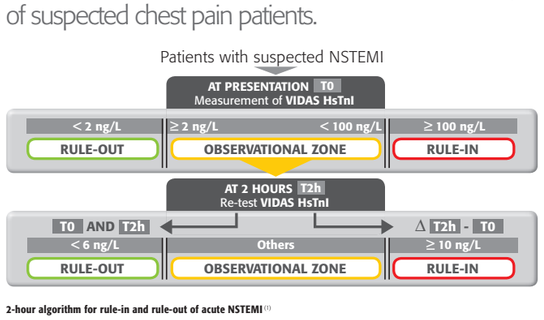
A comprehensive approach to cardiac patient management

ACUTE CORONARY SYNDROME (ACS)

VIDAS® High sensitive Troponin I

This assay is an aid in the diagnosis of myocardial infraction and in the risk stratification of patients with symptoms suggestive of ACS with respect to relative risk of all-cause mortality and major adverse cardiac events (MACE) consisting of MI revascularization, at 30 days. VIDAS® High sensitive Troponin I offers analytical and clinical performances in accordance with guidelines [1]:

- CV=7%
- accelerated and validated algorithm for delivering a diagnosis in only 2 hours - safe rule-out and accurate rule-in - of acute Myocardial Infarction (Non ST Elevation Myocardial Infarction) in the vast majority (70%) of suspected chest pain patients.



2-hour algorithm for rule-in and rule-out of acute NSTEMI [1]

HEART FAILURE (HF)

VIDAS® NT-proBNP2

Early diagnosis of heart failure is key to improving patient outcome. Natriuretic peptides are recommended in international guidelines as a biomarker to rule out Heart Failure.[1]

VIDAS® Galectin-3

Testing for elevated blood levels of galectin-3 allows an aid in diagnosis of chronic heart failure patients and identifies those with a 2 to 3 times higher risk of re-hospitalization or mortality. [2-4]

1. Eur Heart J. 2016; 37: 267-315.
2. Ponikowski P, et al. Eur Heart J. 2016 Jul 14;37(27):2129-200.
3. Lok DJ, *et al.* Clin Res Cardiol. 2010;99:323-8.
4. de Boer RA, *et al.* Ann Med. 2011;43:60-8.
5. Felker GM, *et al.* Circ Heart Fail. 2012;5:72-78.

CARDIAC PANEL

High sensitive Troponin I, NT-proBNP2, Galectin-3, CK-MB, Myoglobin, Digoxin

VENOUS THROMBOEMBOLISM (VTE)

VIDAS® D-Dimer EXCLUSION™ II The reference to exclude VTE

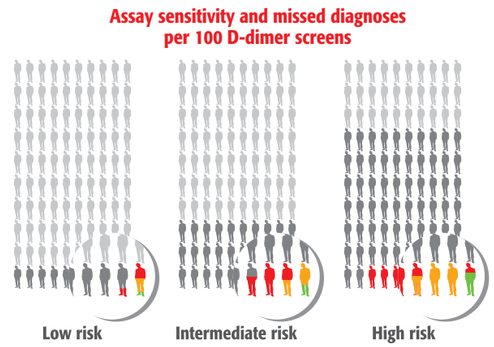
Two key steps are essential for cost-efficient and safe exclusion of VTE.[1,2]

Clinical assessment using validated pre-test probability (PTP) classifies patient risk for VTE [3-5] and should be followed by D-Dimer testing using a validated high-sensitivity assay (≥ 97%).[6]

The VIDAS® D-Dimer test safely excludes outpatients with suspected VTE.

VIDAS® D-Dimer Exclusion™ II with sensitivity of > 99% (NPV* > 99%) allows the safe exclusion of up to 50% of outpatients with suspected VTE and reduces missed diagnoses.

VIDAS® D-Dimer has the most published studies supporting it, including 7 prospective outcome studies (>8,000 patients enrolled) [7]. It is widely considered to be the Gold Standard and is FDA cleared for VTE exclusion.



D-Dimer is not recommended for exclusion in High PTP group

* Negative Predictive Value.

1. Righini M, *et al.* J Thromb Haemost. 2007;5:1869-7.
2. Ten Cate-Hoek AJ, *et al.* J Thromb Haemost. 2005;3:2465-70.
3. Wells PS, *et al.* N Engl J Med. 2003;349:1227-35.
4. Wells PS, *et al.* Thromb Haemost. 2000;83:416-20.
5. Le Gal G, *et al.* Ann Intern Med. 2006;144:165-71.
6. Wayne PA. CLSI document H59-A. Clinical and Laboratory Standards Institute, PA, USA, 2011.
7. Carrier M, *et al.* Thromb Haemost. 2009;101:886-92.

HEMOSTASIS PANEL

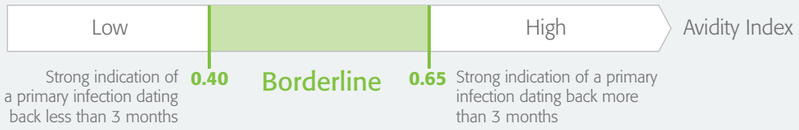
D-Dimer Exclusion™ II, Protein C, vWF

ToRC

Serenity throughout pregnancy

With the VIDAS® ToRC panel your lab has a complete solution for the screening and diagnosis of Toxoplasmosis, Rubella and Cytomegalovirus infections in pregnant women and newborns. This includes **high performance CMV and toxoplasmosis IgG Avidity assays** which are of upmost importance to help distinguish between recent and past infections if maternal IgM and IgG are both positive during pregnancy.

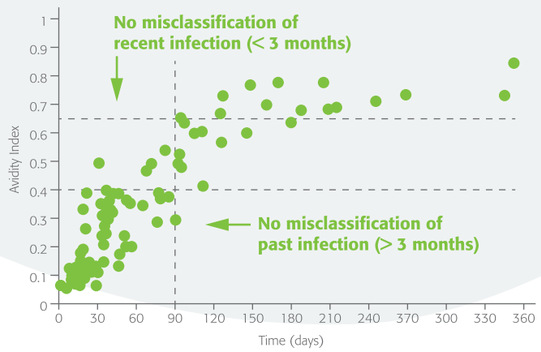
VIDAS® CMV IgG AVIDITY II



The VIDAS® CMV IgG Avidity assay correlates very well with the time from onset of infection.[1]

A study conducted to assess VIDAS® CMV IgG Avidity II maturation kinetics on 135 sequential samples from 31 patients[1] confirmed a very good correlation to clinical diagnosis.

"The VIDAS assay was the most regular, showing the best correlation over time from onset of infection. No sample was wrongly misclassified.[1]"



1. C. Vauloup-Fellous *et al.* Re-evaluation of the VIDAS® cytomegalovirus (CMV) IgG avidity assay: determination of new cut-off values based on the study of kinetics of CMV-IgG maturation. J Clin Virol 2013; 56(2): 118-23.

ToRC PANEL

TOXO: **TOXO IgG II, TOXO IgM, TOXO Competition, TOXO IgG Avidity,**

CMV: **CMV IgG, CMV IgM, CMV IgG Avidity II,**

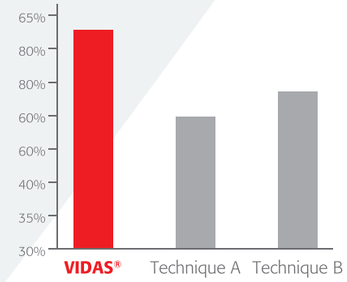
RUBELLA: **RUB IgG II, RUB IgM**

VIDAS® TOXO IgG AVIDITY

The most important parameter required for a Toxo IgG avidity assay is the ability to provide high avidity values for past toxoplasmosis infection.[2]

VIDAS® TOXO IgG Avidity identifies more old infections than other commonly-used tests.

2. Murat J-B., *et al.* Comparison of the VIDAS System and Two Recent Fully Automated Assays for Diagnosis and Follow-Up of Toxoplasmosis in Pregnant Women and Newborns. Clin Vaccine Immunol 2013;20(8):1203-12.



Percentage of samples with high Toxoplasmosis IgG avidity values with different techniques[2]

"The VIDAS TOXO IgG Avidity had the best performance for the diagnosis of latent toxoplasmosis."

Villard, O., *et al.* Comparison of Four Commercially Available Avidity Tests for Toxoplasma gondii-Specific IgG Antibodies. Clin Vaccine Immunol, 2013; 20(2): 197-204.

INFECTIOUS MONONUCLEOSIS EBV

Reassuring when symptoms are unclear

The VIDAS® EBV panel consists of 4 EBV-specific markers in 3 tests to establish the stage of infection:

- ➔ Absence of infection
- ➔ Primary infection
- ➔ Past infection

EBV PANEL

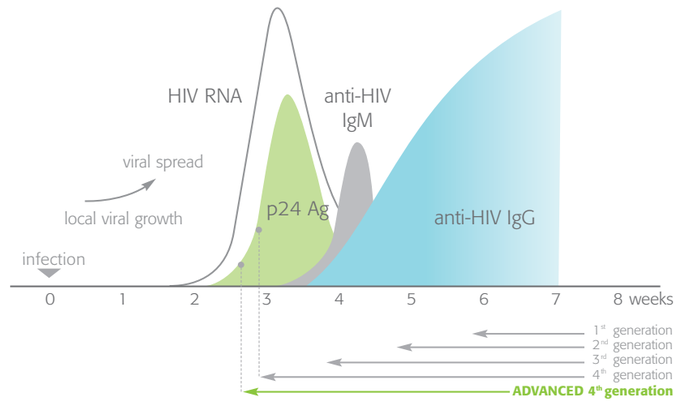
EBV VCA IgM,
EBV VCA/EA IgG,
EBV EBNA IgG

HIV

Ensuring early diagnosis

The VIDAS® HIV panel is a combination of advanced 4th generation tests based on a unique assay concept.

It offers one of the highest levels of sensitivity currently available, allowing earlier detection of HIV infection and the confirmation of the presence of p24 Ag - just two weeks after exposure to the virus. This rapid detection can make the difference in reducing transmission and allows clinicians to provide appropriate care as soon as possible.



HIV PANEL

HIV DUO Ultra, HIV DUO Quick, HIV P24 II, HIV P24 II Confirmation

HEPATITIS

Access to hepatitis profile made easy

Viral hepatitis infections are a major public health problem across the globe, affecting hundreds of millions worldwide and killing some 1.4 million every year.[1]

The VIDAS® Hepatitis panel covers all the essential parameters for rapid and precise differential diagnosis of HAV, HBV and HCV infections, supporting appropriate treatment and enhanced patient care.

VIDAS® HBs Ag Ultra

Ultra sensitive test enabling to reduce the serological window and detect hidden infections.

High capacity for the detection of various mutants/variants in whole blood samples.[2]

VIDAS® Anti-HCV

Sensitive 3rd generation assay that detects all 6 HCV genotypes, ensuring clear and confident diagnosis of Hepatitis C, with results available in 40 minutes.

The solid performance of the VIDAS® anti-HCV assay in clinical trials confirms the high level of quality labs have come to expect from VIDAS, for complete peace of mind.

Diagnostic Sensitivity (95% Confidence Interval)	
HCV positive / HIV negative patients (n = 254)	**100%** [98.56% - 100%]
HCV positive / HIV positive patients (n = 61*)	**98.36%** [91.20% - 99.96%]
HCV positive / (HIV unknow) patients (n = 124)	**100%** [97.07% - 100%]
Total population (n = 439*)	**99.77%** [98.74% - 99.99%]

* 1 patient who was not detected using Anti-HCV either had a low antibody level or was not detected using equivalent method.

1. World Health Organisation, World Hepatitis Day Campaign 2013.
2. Servant-Delmas *et al.*, Variable capacity of 13 hepatitis B virus surface antigen assays for the detection of HBsAg mutants in blood samples, Journal of Clinical Virology, 53 (2012) 338-345.

HEPATITIS PANEL

HEPATITIS A: **HAV IgM, Anti-HAV Total**

HEPATITIS B: **HBs Ag Ultra, HBs Ag Ultra Confirmation, Anti-HBs Total II, Anti-HBc Total II, HBc IgM II, HBe/Anti-HBe**

HEPATITIS C: **Anti-HCV**

LYME DISEASE

Get the right diagnosis

Lyme Borreliosis is one of the world's most common and rapidly spreading tick-borne diseases.

The VIDAS® Lyme IgM and IgG panel allows your lab to establish a reliable serological profile in just 27 minutes. It is an aid for rapid differential diagnosis and easier classification of Lyme borreliosis. This ensures optimized patient treatment according to the stage of infection and rational use of antibiotics.

The good specificity and sensitivity of the VIDAS® Lyme IgM and IgG panel mean it detects all major pathogenic strains [1], reducing the need for additional testing. Studies have demonstrated the panel's good performance in areas with both high and low prevalence.

1. *Borrelia burgdorferi sensu stricto, Borrelia afzelii, Borrelia garinii.*

"Excellent specificity observed with VIDAS Lyme IgG on sera from low-endemic area."

Dr. Olivier Péter, Valais Hospital – Central Institute Microbiology and Infectious Diseases, Sion Partner organization of the National Reference Center for Tick-Borne Diseases, Neuchâtel, Switzerland

H. PYLORI

Non-invasive detection of *H. pylori* infection

The *H. pylori* bacteria is one of the most common causes of stomach ulcers and may increase the risk of stomach cancer.

The VIDAS *H. pylori* IgG test is a qualitative, non-invasive test providing results in just 40 minutes to aid diagnosis of *H. pylori* infection in symptomatic adults. Easy to perform, with kits adapted to low volume testing, it detects anti-*Helicobacter pylori* IgG antibodies in human serum or plasma.

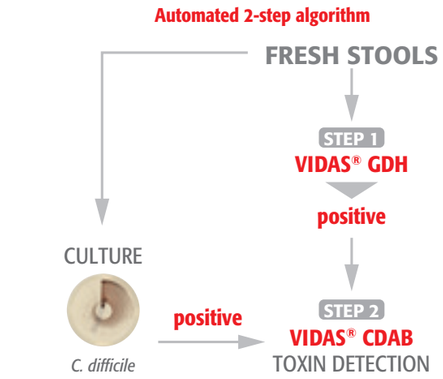
C. DIFFICILE

Simplify diagnosis and outbreak management through automation

Clostridium difficile accounts for up to 25% of cases of healthcare-associated diarrhea and is the primary cause of antibiotic-associated colitis.[1] Management of *C. difficile* infection requires patient isolation, extensive treatment and often leads to a longer hospital stay.

Part of the comprehensive bioMérieux *C. difficile* solution, the VIDAS® *C. difficile* automated panel rapidly gives you the information you need to help identify and contain the spread of the infection during sporadic or epidemic outbreaks.

The VIDAS® *C. difficile* panel proposes a two-step algorithm for the diagnosis of *C. difficile* infection: the VIDAS® *C. difficile* GDH assay provides highly sensitive screening of the *C. difficile* antigen, glutamate dehydrogenase (GDH) in stool specimens, followed by confirmation of positive GDH samples with VIDAS® *C. difficile* Toxin A & B. [1]



1. Bartlett JG. Clinical Practice. Antibiotic-associated diarrhea. N Engl J Med. 2002;346:334-349.

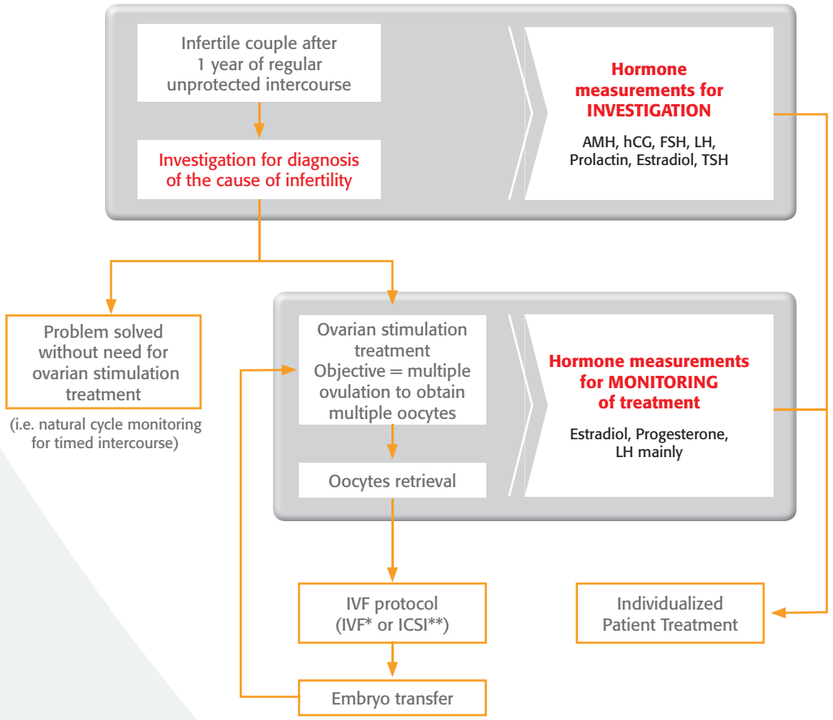
OTHER INFECTIOUS DISEASES ASSAYS

C. difficile GDH, _C. difficile_ Toxin A & B
Lyme IgM, Lyme IgG,
***H. pylori* IgG**
Measles IgG, Mumps IgG, Varicella Zoster IgG

INFERTILITY MANAGEMENT

When nature needs a little help

Hormone measurements are essential to help in the correct diagnosis of the cause of infertility and to monitor the progress of ovarian stimulation.



* *in vitro* fertilization
** Intracytoplasmic Sperm Injection

FERTILITY PANEL
AMH, LH, FSH
Estradiol II, Progesterone
Testosterone II, Prolactin, hCG

The VIDAS® Fertility solution makes testing simple for Fertility clinics

The VIDAS® Fertility panel is a convenient solution for on-site testing for the investigation and treatment of infertility. It includes the key parameters in this field - LH, FSH, Progesterone, Estradiol, Testosterone, Prolactin, hCG and now AMH*.

As an indicator of the ovarian follicle reserve, AMH is useful in different contexts all along the reproductive lifespan in women:
- Personalization of infertility management (IVF/ART)
- Detection of ovarian dysfunction (Polycystic Ovary Syndrome, Premature ovarian failure…)
- Monitoring of ovarian damage further to surgery or gonadotoxic therapies

Tests for infectious diseases can also be performed on the same instrument:
HIV, Hepatitis, Toxoplasmosis, Rubella, Cytomegalovirus. This is important for prevention both before and during pregnancy and to allow gamete storage.

Clinical evaluation of VIDAS® Estradiol and VIDAS® Progesterone has confirmed the reliability of both assays for use in evaluating natural cycles and monitoring ovarian superovulation[1]:

"VIDAS E2 and PRG assays are precise and sensitive tools for evaluating natural cycles […] and for monitoring ovarian superovulation.[1]"

1. E. Anckaert *et al.* Clinical Validation of a Fully Automated 17β-Estradiol and Progesterone Assay (VIDAS®) for Use in Monitoring Assisted Reproduction Treatment. Clin Chem Lab Med 2002; 40(8):824-831.
* VIDAS® AMH is not available in the following countries, states and regions: Armenia, Australia, Austria, Azerbaijan, Belarus, Belgium, Canada, Denmark, France, Germany, Hong-Kong, Ireland, Israel, Italy, Japan, Kazakhstan, Kyrgyzstan, Liechtenstein, Moldavia, New Zealand, Portugal, Russia, Spain, Switzerland, Tajikistan, The Netherlands, Turkey, Turkmenistan, United Kingdom.

THYROID

Targeted treatment starts with accurate profiling

The VIDAS® Thyroid panel includes all the parameters your lab needs for more accurate, rapid diagnosis and follow-up of thyroid disorders. As well as the key TSH, FT4 and FT3 assays, the panel now also includes VIDAS® Anti-TPO and VIDAS® Anti-Tg tests, which are important when further investigation of thyroid dysfunction is required.

THYROID PANEL
TSH, T3, T4, FT3, FT4, Anti-TPO, Anti-Tg

TUMOR MARKERS

Accurate monitoring for better patient management

The VIDAS® range of tumor markers offers your lab a rapid, automated, and reliable solution to meet your clinicians' main requirements.

TUMOR MARKER PANEL
AFP, CEA (S), CA 15-3®, CA 19-9™, CA 125 II™, FPSA, TPSA

ALLERGY

Knowing the cause helps bring relief

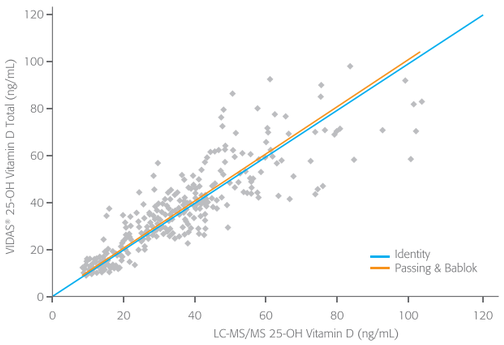
The VIDAS® TOTAL IgE assay is the first global screening step in diagnosis of allergic diseases. A high concentration of IgE (adults > 150 kIU/L | children under 3 > 40 kIU/L, then increasing to reach adult values at about 8 years old) indicates a high probability of allergy.

ALLERGY PANEL
Total IgE

VITAMIN D TOTAL

Reach out for optimum wellness

VIDAS® 25 OH Vitamin D Total detects both vitamin D2 and D3 for reliable results and is easy to use, with no sample pretreatment. All reagents are included in a single strip and have very good correlation with LC-MS/MS.



OTHER ASSAYS
Vitamin D, ß2 Microglobulin, Cortisol S, Ferritin

SERVICES

As a VIDAS® user, you can also benefit from a range of services tailored to ensure your lab's continued development.

Skilled system engineers and application specialists available wherever your VIDAS® instrument is installed.

Our remote instrument support services provide you with immediate solutions for VIDAS® and VIDAS® 3 instruments.

myQC Quality Control program gives you a large statistical potential for QC plan assessment.

Our validation package includes all the documentation required to validate your instrument.

Support provided to accompany you on your **lab certification process**.

Online training sessions complement VIDAS® on-site service, and offer continuous improvement for your lab teams.

myQC SOLUTION!

Based on your lab risk analysis and quality control plan, internal Quality Control is essential to:

- sustain your quality management system,
- obtain and maintain ISO 15 189 certification

bioMérieux offers a complete solution: internal quality control and support with a single point of contact for greater efficiency.

myQC CONTROL TEST KITS

- ✓ myQC Routine + TM
- ✓ myQC Cardiac
- ✓ myQC Specialty

Name	myQC Routine + TM	myQC Cardiac	myQC Specialty
Common analytes	TSH, TSH3, T4, FT4, T3, FT3, Testosterone, Progesterone, HCG, Ferritin, ß2 Microglobulin, AFP, LH, FSH, Estradiol, Cortisol, FPSA, TPSA, IgE, Prolactin, CEA, CA 125, CA 19-9, CA 15-3	Myoglobin, NT-proBNP, D-Dimer, High sensitive Troponin I	B.R.A.H.M.S PCT, Anti-Tg, Anti-TPO

myQC SERVICES

In addition to standard customer support, myQC services are part of a global offer designed by bioMérieux Performance Solutions™ with accreditation support through method verification, QC analysis and e-learning.

myvidas.com

bioMérieux S.A.
69280 Marcy l'Etoile
France
Tel.: +33 (0)4 78 87 20 00
Fax: +33 (0)4 78 87 20 90

www.biomerieux.com
www.biomerieux-diagnostics.com

BIOMÉRIEUX

EU DECLARATION OF CONFORMITY

1. Product model/product:
   Ref. 410416 mini VIDAS®
   Ref. 410417 VIDAS®

2. Name and address of the manufacturer or his authorised representative:
   MANUFACTURER : **bioMérieux S.A.**
   376 Chemin de l'Orme
   69280 - MARCY L'ETOILE – FRANCE

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration:
   In Vitro Diagnostic Medical Device

5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation(s):
   Directive 2011/65/EU – RoHS

6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
   EN 50581: 2012

7. Where applicable, the notified body:
   -

8. Where applicable, description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity:
   -

9. Additional information:
   VIDAS Family RoHS II Implementation Summary Report: SV-VD008

Signed for and on behalf of: **bioMérieux SA.**

Place : Craponne
Date : July 22th, 2016

Name & position : **Catherine Fritsch**
Regulatory Affairs Director
Immunology Unit

Signature :

CE

Български (bg)

ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ

1. одел на продукт/продукт:
2. Наименование и адрес на производителя или на неговия упълномощен представител:
3.Настоящата декларация за съответствие е издадена на отговорността на производителя:
4.Предмет на декларацията (идентификация на електрическите съоръжения, позволяваща проследяването им. Това може да включва достатъчно ясно цветно изображение, когато това е необходимо, за да позволи идентификацията на електрическите съоръжения):
5.Предметът на декларацията, описан по-горе, отговаря на съответното законодателство на Съюза за хармонизация:
6.Позоваване на използваните хармонизирани стандарти или позоваване на други технически спецификации, по отношение на които се декларира съответствие:
7. [2014/53/EU] [2014/30/EU] Когато е приложимо, нотифицираният орган… (наименование, номер)… извърши … (описание на извършеното) … и издаде сертификата за ЕС изследване на типа: …
[2014/68/EU] Когато е целесъобразно, име, адрес и номер на нотифицирания орган, който е извършил оценяването на съответствието, и номер на издадения сертификат, както и позоваване на сертификата за ЕС изследване на типа - изследване на типа произведен продукт, сертификата за ЕС изследване на типа - изследване на проекта на типа, сертификата за ЕС изследване на проекта или сертификата за съответствие.
8. [2014/53/EU] Когато е приложимо, описание на принадлежностите и компонентите, включително софтуер, които позволяват на радиосъоръжението да работи по предназначение и които са обхванати от ЕС декларацията за съответствие:
9.Допълнителна информация:
Подписано за и от името на:
(място и дата на издаване):
(име, длъжност) (подпис):

Deutsch (de)

EU-KONFORMITÄTSERKLÄRUNG

1. Produktmodell/Produkt:
2. Name und Anschrift des Herstellers oder seines Bevollmächtigten:
3. Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller.
4. Gegenstand der Erklärung (Bezeichnung des elektrischen Betriebsmittels zwecks Rückverfolgbarkeit; sie kann eine hinreichend deutliche Farbabbildung enthalten, wenn dies zur Identifikation des elektrischen Betriebsmittels notwendig ist.):
5. Der oben beschriebene Gegenstand der Erklärung erfüllt die einschlägigen Harmonisierungsrechtsvorschriften der Union:
6. Angabe der einschlägigen harmonisierten Normen, die zugrunde gelegt wurden, oder Angabe der anderen technischen Spezifikationen, in Bezug auf die die Konformität erklärt wird:
7. [2014/53/EU] [2014/30/EU] Falls zutreffend — Die notifizierte Stelle … (Name, Kennnummer) hat … (Beschreibung ihrer Mitwirkung) … und folgende EU-Baumusterprüfbescheinigung ausgestellt:
[2014/68/EU] Gegebenenfalls Name, Anschrift und Nummer der notifizierten Stelle, die die Konformitätsbewertung vorgenommen hat, Nummer der ausgestellten Bescheinigung und Verweis auf die EU-Baumusterprüfbescheinigung (Baumuster), die EU-Baumusterprüfbescheinigung (Entwurfsmuster), die EU-Entwurfsprüfbescheinigung oder die Konformitätsbescheinigung.
8. [2014/53/EU] Falls vorhanden — Beschreibung des Zubehörs und der Bestandteile einschließlich Software, die den bestimmungsgemäßen Betrieb der Funkanlage ermöglichen und von der EU-Konformitätserklärung erfasst werden:
9. Zusatzangaben:
Unterzeichnet für und im Namen von:
(Ort und Datum der Ausstellung):
(Name, Funktion) (Unterschrift):

English (en)

EU DECLARATION OF CONFORMITY

1. Product model/product:
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of electrical equipment allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the electrical equipment):
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
7. [2014/53/EU] [2014/30/EU] Where applicable, the notified body … (name, number) … performed … (description of intervention) … and issued the EU-type examination certificate: …
[2014/68/EU] Where appropriate, the name, address and number of the notified body which carried out the conformity assessment and the number of the certificate issued, and a reference to the EU-type examination certificate – production type, EU-type examination certificate – design type, EU design examination certificate or certificate of conformity.
8. [2014/53/EU] Where applicable, description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity:
9. Additional information:
Signed for and on behalf of: …
(place and date of issue):
(name, function) (signature):

hrvatski (hr)

EU IZJAVA O SUKLADNOSTI

1. Uzorak proizvoda/proizvod:
2. Ime i adresa proizvođača ili njegovog ovlaštenog zastupnika:
3. Za izdavanje EU izjave o sukladnosti odgovoran je isključivo proizvođač.
4. Predmet izjave (identifikacija električne opreme koja omogućava sljedivost. Može uključivati dovoljno jasnu sliku u boji ako je potrebno za identifikaciju električne opreme).
5. Predmet navedene izjave u skladu je s mjerodavnim zakonodavstvom Unije o usklađivanju:
6. Pozivanja na relevantne primijenjene usklađene norme ili pozivanja na druge tehničke specifikacije u vezi s kojima se izjavljuje sukladnost:
7. [2014/53/EU] [2014/30/EU] Prema potrebi, prijavljeno tijelo ... (naziv, broj) … provelo je … (opis intervencije) … i izdalo potvrdu o EU ispitivanju tipa: …
[2014/68/EU] gdje je to primjereno, naziv, adresu i broj prijavljenog tijela koje je provelo ocjenu sukladnosti te broj izdane potvrde i upućivanje na potvrdu o EU-pregledu tipa – vrsti proizvodnje, potvrdu o EU-pregledu tipa – vrsti projektiranja, EU-potvrdu o pregledu projektiranja ili potvrdu o sukladnosti.
8. [2014/53/EU] Prema potrebi, opis dodatne opreme i sastavnica, uključujući softver, koji omogućuju normalan rad radijske opreme koji je obuhvaćen EU izjavom o sukladnosti:
9. Dodatne informacije:
Potpisano za i u ime:
(mjesto i dan izdavanja):
(ime, funkcija) (potpis):

čeština (cs)

EU PROHLÁŠENÍ O SHODĚ

1. Model výrobku/výrobek:
2. Jméno a adresa výrobce nebo jeho zplnomocněného zástupce:
3. Toto prohlášení o shodě se vydává na výhradní odpovědnost výrobce.
4. Předmět prohlášení (identifikace elektrického zařízení umožňující je zpětně vysledovat; může zahrnovat dostatečně zřetelné barevné vyobrazení, je-li to pro identifikaci daného elektrického zařízení nezbytné):
5. Výše popsaný předmět prohlášení je ve shodě s příslušnými harmonizačními právními předpisy Unie:
6. Odkazy na příslušné harmonizované normy, které byly použity, nebo na jiné technické specifikace, na jejichž základě se shoda prohlašuje:
7. [2014/53/EU] [2014/30/EU] Případně: oznámený subjekt ... (název, číslo) … provedl … (popis opatření) … a vydal certifikát EU přezkoušení typu: …
[2014/68/EU] Případně název, adresa a číslo oznámeného subjektu, který provedl posouzení shody, a číslo vydaného certifikátu a odkaz na certifikát EU přezkoušení výrobního typu, certifikát EU přezkoušení konstrukčního typu, certifikát EU přezkoumání návrhu nebo certifikát shody.
8. [2014/53/EU] V příslušných případech popis příslušenství a součástí, včetně softwaru, které umožňují zamýšlené fungování rádiového zařízení v souladu s EU prohlášením o shodě:
9.Další informace:
Podepsáno za a jménem:
(místo a datum vydání):
(jméno, funkce) (podpis):

eesti keel (et)

ELi VASTAVUSDEKLARATSIOON

1. Toote mudel/toode:
2. Tootja või tema volitatud esindaja nimi ja aadress:
3. Käesolev vastavausdeklaratsioon on välja antud tootja ainuvastutusel.
4. Deklareeritav toode (elektriseadme identifitseerimine, mis võimaldab toodet jälgida; vajaduse korral võib elektriseadme identifitseerimiseks lisada piisavalt selge värvilise kujutise):
5.Eelkirjeldatud deklareeritav toode on kooskõlas asjaomaste liidu ühtlustamisaktidega:
6. Viited kasutatud harmoneeritud standarditele või viited muudele tehnilistele spetsifikatsioonidele, millele vastavust deklareeritakse:
7. [2014/53/EU] [2014/30/EU] Vajaduse korral: teavitatud asutus … (nimi, number) … teostas … (tegevuse kirjeldus) … ja andis välja ELi tüübihindamistõendi: …
[2014/68/EU] Asjakohasel juhul vastavushindamise teostanud teavitatud asutuse nimi, aadress ja identifitseerimisnumber ning välja antud sertifikaadi number, samuti viide ELi tüübihindamissertifikaadile (toote tüüp), ELi tüübihindamissertifikaadile (konstruktsioonitüüp), ELi konstruktsioonihindamissertifikaadile või vastavussertifikaadile.
8. [2014/53/EU] Vajaduse korral selliste tarvikute ja osade, samuti tarkvara kirjeldus, mis võimaldavad raadioseadet kasutada ettenähtud otstarbel ja kooskõlas ELi vastavusdeklaratsiooniga:
9. Lisateave:
Alla kirjutanud (kelle poolt ja nimel):
(väljaandmise koht ja kuupäev):
(nimi, ametinimetus) (allkiri):

español (es)

DECLARACIÓN UE DE CONFORMIDAD

1. Modelo de producto/producto:
2. Nombre y dirección del fabricante o de su representante autorizado:
3. La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante.
4. Objeto de la declaración (identificación del material eléctrico que permita la trazabilidad. Podrá incluir una imagen en color de nitidez suficiente cuando resulte necesario para permitir la identificación del material eléctrico):
5. El objeto de la declaración descrita anteriormente es conforme con la legislación de armonización pertinente de la Unión:
6. Referencias a las normas armonizadas pertinentes utilizadas, o referencias a las otras especificaciones técnicas respecto a las cuales se declara la conformidad:
7. [2014/53/EU] [2014/30/EU] Cuando proceda: El organismo notificado … (nombre, número) … ha efectuado … (descripción de la intervención) … y expedido el certificado de examen UE de tipo: …
[2014/68/EU] En su caso, el nombre, la dirección y el número del organismo notificado que haya efectuado la evaluación de la conformidad y el número de certificado expedido, y una referencia al certificado de examen UE de tipo —tipo de producción, al certificado de examen UE de tipo— tipo de diseño, al certificado de examen UE de diseño, o al certificado de conformidad.
8. [2014/53/EU] Cuando proceda, descripción de los accesorios y componentes, incluido el software, que permiten que el equipo radioeléctrico funcione como estaba previsto y esté amparado por la declaración UE de conformidad:
9. Información adicional:
Firmado en nombre de:
(lugar y fecha de expedición):
(nombre, cargo) (firma):

italiano (it)

DICHIARAZIONE DI CONFORMITÀ UE

1. Modello di prodotto/prodotto:
2. Nome e indirizzo del fabbricante o del suo rappresentante autorizzato:
3. La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante.
4. Oggetto della dichiarazione (identificazione del materiale elettrico che ne consenta la rintracciabilità; può comprendere un'immagine a colori di chiarezza sufficiente se necessario per l'identificazione del materiale elettrico):
5. L'oggetto della dichiarazione di cui sopra è conforme alla pertinente normativa di armonizzazione dell'Unione:
6. Riferimento alle pertinenti norme armonizzate utilizzate o riferimenti alle altre specifiche tecniche in relazione alle quali è dichiarata la conformità:
7. [2014/53/EU] [2014/30/EU] Se del caso, l'organismo notificato … (denominazione, numero) … ha effettuato … (descrizione dell'intervento) … e rilasciato il certificato di esame UE del tipo: …
[2014/68/EU] Eventualmente, il nome, l'indirizzo e il numero dell'organismo notificato che ha effettuato la valutazione di conformità e il numero del certificato rilasciato, nonché un riferimento al certificato di esame UE del tipo - tipo di produzione, certificato di esame UE del tipo, tipo di progetto, certificato di esame UE del progetto o certificato di conformità.
8. [2014/53/EU] Se del caso, una descrizione degli accessori e dei componenti inclusi nella dichiarazione di conformità UE, compreso il software, che consentono all'apparecchiatura radio di funzionare come previsto:
9. Informazioni supplementari:
Firmato a nome e per conto di:
(luogo e data del rilascio):
(nome, funzione) (firma):

dansk (da)

EU-OVERENSSTEMMELSESERKLÆRING
1. Produktmodel/produkt:
2. Navn og adresse på fabrikanten eller dennes bemyndigede repræsentant:
3. Denne overensstemmelseserklæring udstedes på fabrikantens ansvar.
4. Erklæringens genstand (identifikation af det elektriske materiel, så det kan spores; den kan indeholde et farvebillede, der er tilstrækkelig klart, hvis det er nødvendigt for at muliggøre identifikation af det elektriske materiel):
5. Genstanden for erklæringen, som beskrevet ovenfor, er i overensstemmelse med den relevante EU-harmoniseringslovgivning:
6. Referencer til de relevante anvendte harmoniserede standarder eller til de andre tekniske specifikationer, som der erklæres overensstemmelse med:
7. [2014/53/EU] [2014/30/EU] Hvor det er relevant, det bemyndigede organ … (navn, nummer) har foretaget … (beskrivelse af aktiviteten) … og udstedt EU-typeafprøvningsattest: …
[2014/68/EU] Hvor det er relevant navn, adresse og nummer på det bemyndigede organ, der har foretaget overensstemmelsesvurderingen, og nummeret på den udstedte attest og en henvisning til EU-typeafprøvningsattesten — produktionstype, EU-typeafprøvningsattesten — konstruktionstype, EU-konstruktionsafprøvningsattesten eller overensstemmelsesattesten.
8. [2014/53/EU] I givet fald beskrivelse af tilbehør og komponenter, herunder software, som får radioudstyret til at fungere efter hensigten og er dækket af EU-overensstemmelseserklæringen:
9. Supplerende oplysninger:
Underskrevet for og på vegne af:
(udstedelsessted og -dato):
(navn, stilling) (underskrift):

ελληνικά (el)

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ
1. Μοντέλο προϊόντος / Προϊόν:
2. Επωνυμία και διεύθυνση του κατασκευαστή ή του εξουσιοδοτημένου αντιπροσώπου του:
3. Η παρούσα δήλωση συμμόρφωσης εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή.
4. Στόχος της δήλωσης (ταυτοποίηση ηλεκτρολογικού υλικού που επιτρέπει την ιχνηλασιμότητα· μπορεί να περιλαμβάνει έγχρωμη εικόνα επαρκούς διαύγειας όταν αυτό είναι απαραίτητο για την ταυτοποίηση του ηλεκτρολογικού υλικού):
5. Ο στόχος της δήλωσης που περιγράφεται παραπάνω είναι σύμφωνος με τη σχετική ενωσιακή νομοθεσία εναρμόνισης:
6. Μνεία των σχετικών εναρμονισμένων προτύπων που χρησιμοποιήθηκαν ή μνεία των λοιπών τεχνικών προδιαγραφών σε σχέση με τις οποίες δηλώνεται η συμμόρφωση:
7. [2014/53/EU] [2014/30/EU] Όπου έχει εφαρμογή, ο κοινοποιημένος οργανισμός … (ονομασία, αριθμός) … πραγματοποίησε … (περιγραφή της παρέμβασης) … και εξέδωσε το πιστοποιητικό εξέτασης τύπου ΕΕ: …
[2014/68/EU] Κατά περίπτωση, όνομα, διεύθυνση και αριθμός του κοινοποιημένου οργανισμού που διενέργησε την αξιολόγηση της συμμόρφωσης και αριθμός του πιστοποιητικού που χορηγήθηκε, καθώς και παραπομπή στο πιστοποιητικό εξέτασης τύπου ΕΕ – τύπος παραγωγής, στο πιστοποιητικό εξέτασης τύπου ΕΕ – τύπος σχεδίασης ή στο πιστοποιητικό συμμόρφωσης.
8. [2014/53/EU] Όπου έχει εφαρμογή, περιγραφή των παρελκόμενων και εξαρτημάτων, συμπεριλαμβανομένου του λογισμικού, που επιτρέπουν στον ραδιοεξοπλισμό να λειτουργεί όπως προβλέπεται και που καλύπτονται από τη δήλωση συμμόρφωσης:
9. Συμπληρωματικές πληροφορίες:
Υπογραφή για λογαριασμό και εξ ονόματος:
(τόπος και ημερομηνία έκδοσης):
(όνομα, θέση) (υπογραφή):

français (fr)

DÉCLARATION UE DE CONFORMITÉ
1. Modèle de produit/produit:
2. Nom et adresse du fabricant ou de son mandataire:
3. La présente déclaration de conformité est établie sous la seule responsabilité du fabricant.
4. Objet de la déclaration (identification du matériel électrique permettant sa traçabilité; si nécessaire, une image couleur suffisamment claire peut être jointe pour identifier le matériel électrique):
5. L'objet de la déclaration décrit ci-dessus est conforme à la législation d'harmonisation de l'Union applicable:
6. Références des normes harmonisées pertinentes appliquées ou des autres spécifications techniques par rapport auxquelles la conformité est déclarée:
7. [2014/53/EU] [2014/30/EU] S'il y a lieu: l'organisme notifié … (nom, numéro) … a réalisé … (description de l'intervention) … et a délivré le certificat d'examen UE de type: …
[2014/68/EU] Le cas échéant, le nom, l'adresse et le numéro de l'organisme notifié ayant effectué l'évaluation de conformité et le numéro de l'attestation délivrée, et un renvoi à l'attestation d'examen UE de type — type de fabrication, à l'attestation d'examen UE de type — type de conception, à l'attestation d'examen UE de la conception ou au certificat de conformité.
8. [2014/53/EU] S'il y a lieu, description des accessoires et des éléments (y compris logiciels) qui permettent à l'équipement radioélectrique de fonctionner selon sa destination et qui sont couverts par la déclaration UE de conformité:
9. Informations complémentaires:
Signé par et au nom de:
(date et lieu d'établissement):
(nom, fonction) (signature):

latviešu valoda (lv)

ES ATBILSTĪBAS DEKLARĀCIJA
1. Produkta modelis / produkts:
2. Ražotāja vai viņa pilnvarotā pārstāvja nosaukums un adrese:
3. Šī atbilstības deklarācija ir izdota vienīgi uz ražotāja atbildību.
4. Deklarācijas priekšmets (elektroiekārtas identifikācija, kas nodrošina tās izsekojamību; vajadzības gadījumā tajā var iekļaut pietiekami skaidru krāsainu attēlu, lai elektroiekārtu varētu identificēt):
5. Iepriekš aprakstītais deklarācijas priekšmets atbilst attiecīgajam Savienības saskaņošanas tiesību aktam:
6. Atsauces uz attiecīgajiem izmantotajiem saskaņotajiem standartiem vai uz citām tehniskajām specifikācijām, attiecībā uz ko tiek deklarēta atbilstība:
7. [2014/53/EU] [2014/30/EU] Attiecīgā gadījumā paziņotā struktūra … (nosaukums, numurs) … ir veikusi … (darbības apraksts) … un izdevusi ES tipa pārbaudes sertifikātu: …
[2014/68/EU] Attiecīgā gadījumā – tās paziņotās struktūras nosaukums, adrese un numurs, kura veikusi atbilstības novērtēšanu, un izsniegtā sertifikāta numurs, un atsauce uz ES tipa pārbaudes sertifikātu - produkcijas tipu, ES tipa pārbaudes sertifikātu - projekta tipu, ES projekta pārbaudes sertifikātu vai atbilstības sertifikātu.
8. [2014/53/EU] Attiecīgā gadījumā palīgierīču un komponentu apraksts, ieskaitot programmatūras aprakstu, kas nodrošina radioiekārtas paredzēto darbību un uz ko attiecas ES atbilstības deklarācija:
9. Papildu informācija:
Parakstīts šādas personas vārdā:
(izdošanas vieta un datums):
(vārds, uzvārds, amats) (paraksts):

lietuvių kalba (lt)

ES ATITIKTIES DEKLARACIJA
1. Gaminio modelis / gaminys:
2. Gamintojo arba jo įgaliotojo atstovo pavadinimas ir adresas:
3. Ši atitikties deklaracija išduota tik gamintojo atsakomybe.
4. Deklaracijos objektas (elektros įrenginio identifikaciniai duomenys, pagal kuriuos jį galima atsekti. Gali būti pateikiamas spalvotas atvaizdas, prireikus pakankamai aiškus, kad būtų galima elektros įrenginį identifikuoti):
5. Pirmiau aprašytas deklaracijos objektas atitinka susijusius derinamuosius Sąjungos teisės aktus:
6. Susijusių taikytų darniųjų standartų nuorodos arba kitų techninių specifikacijų, pagal kurias buvo deklaruota atitiktis, nuorodos:
7. [2014/53/EU] [2014/30/EU] Kai taikytina, notifikuotoji įstaiga … (pavadinimas, numeris) … atliko … (dalyvavimo procese aprašymas) ir išdavė ES tipo tyrimo sertifikatą: …
[2014/68/EU] Tam tikrais atvejais atitikties įvertinimą atlikusios notifikuotosios įstaigos pavadinimas, . adresas ir numeris ir išduoto sertifikato numeris bei nuoroda į ES tipo tyrimo sertifikatą – produkcijos tipas, ES tipo tyrimo sertifikatas – projekto tipas, ES projekto tyrimo sertifikatą arba atitikties sertifikatą.
8. [2014/53/EU] Kai taikytina, pagalbinių įtaisų ir komponentų, įskaitant programinę įrangą, kurie leidžia radijo įrenginiams veikti pagal paskirtį ir yra įtraukti į ES atitikties deklaraciją, aprašas:
9. Papildoma informacija:
Už ką ir kieno vardu pasirašyta:
(išdavimo data ir vieta):
(vardas ir pavardė, pareigos) (parašas):

Nederlands (nl)

EU-CONFORMITEITSVERKLARING
1. Product:
2. Naam en adres van de fabrikant of zijn gemachtigde:
3. Deze conformiteitsverklaring wordt verstrekt onder volledige verantwoordelijkheid van de fabrikant.
4. Voorwerp van de verklaring (beschrijving aan de hand waarvan het elektrisch materiaal kan worden getraceerd. Wanneer dat voor de identificatie van het elektrisch apparaat noodzakelijk is, mag er een voldoende duidelijke afbeelding in kleur worden toegevoegd):
5. Het hierboven beschreven voorwerp is in overeenstemming met de desbetreffende harmonisatiewetgeving van de Unie:
6. Vermelding van de toegepaste relevante geharmoniseerde normen of van de overige technische specificaties waarop de conformiteitsverklaring betrekking heeft:
7. [2014/53/EU] [2014/30/EU] (Indien van toepassing) De aangemelde instantie … (naam, nummer) … heeft een … (beschrijving van de werkzaamheden) … uitgevoerd en het certificaat van EU-typeonderzoek … afgegeven:
[2014/68/EU] Indien van toepassing, naam, adres en nummer van de aangemelde instantie die de conformiteitsbeoordeling heeft verricht en nummer van het afgegeven certificaat, en een verwijzing naar het certificaat van EU-typeonderzoek — Productietype, het certificaat van EU-typeonderzoek — Ontwerptype, het certificaat van EU-ontwerponderzoek of het conformiteitscertificaat.
8. [2014/53/EU] Indien van toepassing, beschrijving van de accessoires en onderdelen, met inbegrip van software, die het mogelijk maken dat de radioapparatuur functioneert zoals bedoeld en die onder de EU-conformiteitsverklaring vallen:
9. Aanvullende informatie:
Ondertekend voor en namens:
(plaats en datum van afgifte):
(naam, functie) (handtekening):

Română (ro)

DECLARAȚIA UE DE CONFORMITATE
1. Modelul de produs/produsul:
2. Denumirea și adresa producătorului sau a reprezentantului său autorizat:
3. Prezenta declarație de conformitate este emisă pe răspunderea exclusivă a producătorului.
4. Obiectul declarației (identificarea echipamentului electric permițând trasabilitatea; poate include, dacă este necesar, o imagine color, suficient de clară pentru identificarea echipamentului electric):
5. Obiectul declarației descris mai sus este în conformitate cu legislația relevantă de armonizare a Uniunii:
6. Trimiteri la standardele armonizate relevante folosite sau trimiteri la celelalte specificații tehnice în legătură cu care se declară conformitatea:
7. [2014/53/EU] [2014/30/EU] După caz, organismul notificat … (denumire, număr) ... a efectuat … (descrierea intervenției) și a emis certificatul de examinare UE de tip: …
[2014/68/EU] Dacă este cazul, denumirea, adresa și numărul de telefon al organismului notificat care a efectuat evaluarea de conformitate și numărul certificatului eliberat și o trimitere la certificatul de examinare UE de tip – tip de producție, la certificatul de examinare UE de tip – tip de proiect, la examinarea UE a proiectului sau la certificatul de conformitate.
8. [2014/53/EU] După caz, o descriere a accesoriilor și componentelor, inclusiv a produselor software, care permit echipamentelor radio să funcționeze corespunzător și care sunt incluse în declarația de conformitate:
9. Informații suplimentare:
Semnat pentru și în numele:
(locul și data emiterii):
(numele, funcția) (semnătura):

suomi (fi)

EU-VAATIMUSTENMUKAISUUSVAKUUTUS
1. Tuotemalli/tuote:
2. Valmistajan tai sen valtuutetun edustajan nimi ja osoite:
3. Tämä vaatimustenmukaisuusvakuutus on annettu valmistajan yksinomaisella vastuulla.
4. Vakuutuksen kohde (jäljitettävyyden mahdollistava sähkölaitteen tunniste; voidaan liittää riittävän terävä värikuva, jos se on tarpeen sähkölaitteen tunnistamiseksi):
5. Edellä kuvattu vakuutuksen kohde on asiaa koskevan unionin yhdenmukaistamislainsäädännön vaatimusten mukainen:
6. Viittaus niihin asiaankuuluviin yhdenmukaistettuihin standardeihin, joita on käytetty, tai viittaus muihin teknisiin eritelmiin, joiden perusteella vaatimustenmukaisuusvakuutus on annettu:
7. [2014/53/EU] [2014/30/EU] Tapauksen mukaan ilmoitettu laitos … (nimi, numero) … suoritti … (toimenpiteen kuvaus) … ja antoi EU-tyyppitarkastustodistuksen: …
[2014/68/EU] Tarvittaessa vaatimustenmukaisuuden arviointimenettelyn suorittaneen ilmoitetun laitoksen nimi, osoite ja numero sekä annetun todistuksen numero ja viittaus EU-tyyppitarkastustodistukseen – tuotantotyyppi, EU tyyppitarkastustodistukseen – suunnittelutyyppi, EU-suunnitelmataikastustodistukseen tai vaatimustenmukaisuustodistukseen:
8. [2014/53/EU] Tapauksen mukaan kuvaus lisälaitteista ja osista, myös ohjelmistoista, jotka mahdollistavat radiolaitteen käyttötarkoituksen mukaisen käytön ja jotka EU-vaatimustenmukaisuusvakuutus kattaa:
9. Lisätietoja:
… puolesta allekirjoittanut
(antamispaikka ja -päivämäärä):
(nimi, tehtävä) (allekirjoitus):

magyar (hu)

EU–MEGFELELŐSÉGI NYILATKOZAT

1. Termékmodell/termék:
2. A gyártó vagy meghatalmazott képviselőjének neve és címe:
3. Ezt a megfelelőségi nyilatkozatot a gyártó kizárólagos felelőssége mellett adják ki.
4. A nyilatkozat tárgya (az elektromos berendezés azonosítása a nyomonkövethetőség biztosítására; ez adott esetben tartalmazhatja az elektromos berendezésről az annak megfelelő azonosítását lehetővé tevő színes fényképet is):
5. A fent ismertetett nyilatkozat tárgya megfelel a vonatkozó uniós harmonizációs jogszabályoknak:
6. Az alkalmazott harmonizált szabványokra való hivatkozás vagy az azokra az egyéb műszaki leírásokra való hivatkozás, amelyekkel kapcsolatban megfelelőségi nyilatkozatot tettek.
7. [2014/53/EU] [2014/30/EU] A(z) ... (nevű, számú)... bejelentett szervezet adott esetben elvégezte a(z) ... (a beavatkozás ismertetése) ..., és a következő EU-típusvizsgálati tanúsítványt adta ki: [2014/68/EU] Adott esetben a megfelelőségértékelést végző bejelentett szervezet neve, címe és száma, valamint a kibocsátott tanúsítvány száma, és hivatkozás a gyártási típusra vonatkozó EU-típusvizsgálati tanúsítványra, a tervezési típusra vonatkozó EU-típusvizsgálati tanúsítványra, az EU-tervvizsgálati tanúsítványra vagy a megfelelőségi tanúsítványra.
8. [2014/53/EU] Adott esetben a tartozékok és alkatrészek leírása, ideértve a rádióberendezés rendeltetésszerű használatát lehetővé tévő és az EU-megfelelőségi nyilatkozat hatályába tartozó szoftvereket is:
9. További információk:

A nyilatkozatot a nevében és megbízásából írták alá:
(a kiállítás helye és dátuma):
(név, beosztás) (aláírás):

polski (pl)

DEKLARACJA ZGODNOŚCI UE

1. Model produktu/produkt:
2. Nazwa i adres producenta lub jego upoważnionego przedstawiciela:
3. Niniejsza deklaracja zgodności wydana zostaje na wyłączną odpowiedzialność producenta.
4. Przedmiot deklaracji (identyfikacja produktu umożliwiająca odtworzenie jego historii; może zawierać obraz barwny wystarczająco wyraźny, kiedy konieczne jest zidentyfikowanie sprzętu elektrycznego):
5. Wymieniony powyżej przedmiot niniejszej deklaracji jest zgodny z odnośnymi wymaganiami unijnego prawodawstwa harmonizacyjnego:
6. Odniesienia do odnośnych norm zharmonizowanych, które zastosowano, lub do innych specyfikacji technicznych, w stosunku do których deklarowana jest zgodność:
7. [2014/53/EU] [2014/30/EU] W stosownych przypadkach, jednostka notyfikowana ... (nazwa, numer) ... przeprowadziła ... (opis interwencji) ... i wydała certyfikat badania typu UE: ...
[2014/68/EU] W stosownych przypadkach nazwa, adres i numer jednostki notyfikowanej, która przeprowadziła ocenę zgodności, oraz numer wydanego certyfikatu, a także odniesienie do certyfikatu badania typu UE – typu produkcji, certyfikatu badania typu UE – typu projektu, certyfikatu badania projektu UE lub certyfikatu zgodności.
8. [2014/53/EU] W stosownych przypadkach, opis elementów dodatkowych lub komponentów, w tym oprogramowania, które umożliwiają działanie urządzenia radiowego zgodnie z przeznaczeniem i które są objęte deklaracją zgodności UE:
9. Informacje dodatkowe:

Podpisano w imieniu:
(miejsce i data wydania):
(imię i nazwisko, stanowisko) (podpis):

slovenčina (sk)

EÚ VYHLÁSENIE O ZHODE

1. Typ výrobku/výrobok:
2. Meno a adresa výrobcu alebo jeho splnomocneného zástupcu:
3. Toto vyhlásenie o zhode sa vydáva na výhradnú zodpovednosť výrobcu.
4. Predmet vyhlásenia (identifikácia elektrického zariadenia umožňujúca vysledovateľnosť; v prípade potreby môže obsahovať dostatočne zrozumiteľný farebný obrázok, ktorý umožňuje identifikáciu elektrického zariadenia):
5. Uvedený predmet vyhlásenia je v zhode s príslušnými harmonizačnými právnymi predpismi Únie:
6. Odkazy na príslušné použité harmonizované normy alebo odkazy na iné technické špecifikácie, v súvislosti s ktorými sa vyhlasuje zhoda:
7. [2014/53/EU] [2014/30/EU] Prípadne: notifikovaný orgán ... (názov, číslo) ... vykonal ... (opis zásahu) ... a vydal certifikát EÚ skúšky typu: ...
[2014/68/EU] V príslušnom prípade názov, adresa a číslo notifikovaného orgánu, ktorý vykonal posúdenie zhody a číslo vydaného certifikátu a odkaz na certifikát EÚ skúšky typu – výrobný typ, certifikát EÚ skúšky typu – návrh typu, EÚ certifikát o preskúmaní návrhu alebo certifikát zhody.
8. [2014/53/EU] V príslušných prípadoch opis príslušenstva a komponentov vrátane softvéru, ktoré umožňujú rádiovému zariadeniu fungovať v súlade so zamýšľaným účelom, a na ktoré sa vzťahuje EÚ vyhlásenie o zhode:
9. Doplňujúce informácie:

Podpísané za a v mene:
(miesto a dátum vydania):
(meno, funkcia) (podpis):

svenska (sv)

EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE

1. Produktmodell/produkt:
2. Namn på och adress till tillverkaren eller dennes representant:
3. Denna försäkran om överensstämmelse utfärdas på tillverkarens eget ansvar.
4. Föremål för försäkran (identifiera den elektriska utrustningen så att den kan spåras – den kan innehålla en färgbild som är så tydlig att det vid behov går att identifiera den elektriska utrustningen):
5. Föremålet för försäkran ovan överensstämmer med den relevanta harmoniserade unionslagstiftningen:
6. Hänvisningar till de relevanta harmoniserade standarder som använts eller hänvisningar till de andra tekniska specifikationer enligt vilka överensstämmelsen försäkras:
7. [2014/53/EU] [2014/30/EU] I tillämpliga fall: det anmälda organet ... (namn, nummer) ... har utfört ... (beskrivning av åtgärd) ... och utfärdat EU-typprovningsintyg: ...
[2014/68/EU] I förekommande fall, namn och adress och nummer för det anmälda organ som har utfört bedömningen av överensstämmelse samt intygets nummer, och en hänvisning till EU-typintyget – produktionstyp, EU-typintyget – konstruktionstyp, EU-intyget om konstruktionskontroll eller intyget om överensstämmelse.
8. [2014/53/EU] I förekommande fall en beskrivning av tillbehör och komponenter, inklusive programvara, som gör det möjligt för radioutrustningen att fungera som avsett och som täcks av en EU-försäkran om överensstämmelse:
9. Ytterligare information:

Undertecknat för:
(ort och datum)
(namn, befattning) (namnteckning)

Malti (mt)

DIKJARAZZJONI TAL-KONFORMITÀ TAL-UE

1. Il-prodott:
2. L-isem u l-indirizz tal-manifattur jew tar-rappreżentant awtorizzat tiegħu:
3. Din id-dikjarazzjoni ta' konformità tinħareġ taħt ir-responsabbiltà unika tal-manifattur.
4. L-għan tad-dikjarazzjoni (l-identifikazzjoni tat-tagħmir elettriku li tippermetti t-traċċabbiltà; din tista' tinkludi immaġini bil-kulur ta' ċarezza sufficjenti meta tkun meħtieġa għall-identifikazzjoni tat-tagħmir elettriku).
5. L-għan tad-dikjarazzjoni deskritt hawn fuq huwa konformi mal-leġislazzjoni ta' armonizzazzjoni rilevanti tal-Unjoni:
6. Ir-referenzi għall-istandards armonizzati rilevanti li ntużaw jew ir-referenzi għall-ispeċifikazzjonijiet teknici l-oħra li skonthom qed tiġi ddikjarata l-konformità:
7. [2014/53/EU] [2014/30/EU] Meta applikabbli, il-korp notifikat ... (l-isem, in-numru) ... wettaq... (deskrizzjoni tal-intervent) ... u ħareġ iċ-ċertifikat tal-eżami tat-tip tal-UE: ...
[2014/68/EU] Fejn ikun xieraq, l-isem, l-indirizz u n-numru tal-korp notifikat li jkun wettaq il-valutazzjoni tal-konformità u n-numru taċ-ċertifikat maħruġ, u referenza għaċ-ċertifikat tal-eżami tat-tip tal-UE - it-tip ta' produzzjoni, iċ-ċertifikat tal-eżami tat-tip tal-UE - it-tip ta' disinn, iċ-ċertifikat ta' eżami ta' disinn tal-UE jew iċ-ċertifikat ta' konformità.
8. [2014/53/EU] Fejn applikabbli, deskrizzjoni tal-aċċessorji u il-komponenti, inkluż is-softwer, li jippermettu t-tagħmir tar-radju jopera kif intiż u koperti mid-dikjarazzjoni tal-konformità tal-UE:
9. Informazzjoni addizzjonali:

Iffirmata għal u f'isem:
(post u data tal-ħruġ):
(isem, funzjoni) (firma):

português (pt)

DECLARAÇÃO UE DE CONFORMIDADE

1. Modelo do produto/produto:
2. Nome e endereço do fabricante ou do respetivo mandatário:
3. A presente declaração de conformidade é emitida sob a exclusiva responsabilidade do fabricante.
4. Objeto da declaração (identificação do material elétrico que permita rastreá-lo; se for necessário para a identificação do material elétrico, pode incluir uma imagem a cores suficientemente clara):
5. O objeto da declaração acima descrito está em conformidade com a legislação de harmonização da União aplicável:
6. Referências às normas harmonizadas aplicáveis utilizadas ou a outras especificações técnicas em relação às quais é declarada a conformidade:
7. [2014/53/EU] [2014/30/EU] Se aplicável, o organismo notificado: (nome, número)... efetuou... (descrição da intervenção)... e emitiu o certificado de exame UE de tipo:...
[2014/68/EU] Se aplicável, nome, endereço e número do organismo notificado que efetuou a avaliação da conformidade, assim como o número do certificado emitido, e uma referência ao certificado de exame UE de tipo – tipo de produção, ao certificado de exame UE de tipo – tipo de projeto, ao certificado de exame UE de projeto ou ao certificado de conformidade.
8. [2014/53/EU] Se aplicável, descrição dos acessórios e/ou componentes, incluindo o software, que permitem que o equipamento de rádio funcione conforme o pretendido, abrangidos pela declaração UE de conformidade:
9. Informações complementares:

Assinado por e em nome de:
(local e data de emissão):
(nome, cargo) (assinatura):

slovenščina (sl)

IZJAVA EU O SKLADNOSTI

1. Model proizvoda/proizvod:
2. Ime in naslov proizvajalca ali njegovega pooblaščenega zastopnika:
3. Ta izjava o skladnosti je izdana na lastno odgovornost proizvajalca.
4. Predmet izjave (identifikacija električne opreme, ki omogoča sledljivost; lahko vključuje dovolj jasno barvno sliko, kadar je to potrebno za identifikacijo električne opreme):
5. Predmet navedene izjave je v skladu z ustrezno zakonodajo Unije o harmonizaciji.
6. Sklicevanja na uporabljene relevantne harmonizirane standarde ali sklicevanje na druge tehnične specifikacije v zvezi s katerimi je skladnost deklarirana:
7. [2014/53/EU] [2014/30/EU] Po potrebi je priglašeni organ ... (ime, številka) ... izvedel ... (opis intervencije) ... in izdal certifikat o EU-pregledu tipa: ...
[2014/68/EU] Kadar je ustrezno, ime, naslov in številko priglašenega organa, ki je opravil oceno skladnosti, ter številko izdanega certifikata, in sklicevanje na certifikat o EU- pregledu tipa – tip proizvodnje, certifikat o EU-pregledu tipa – tip načrtovanja, certifikat o EU-pregleda načrta ali certifikat o skladnosti.
8. [2014/53/EU] Po potrebi opise dodatne opreme in komponent, vključno s programsko opremo, ki zagotavljajo namensko delovanje radijske opreme in so zajeti v izjavi EU o skladnosti:
9. Dodatne informacije:

Podpisano za in v imenu:
(kraj in datum izdaje)
(ime, funkcija) (podpis)

BIOMÉRIEUX