



via Scalabrini, 44 - 22100 Como

**Dichiarazione CE di conformità
EC Declaration of conformity**

Dichiariamo qui di seguito che i prodotti:
 We hereby declare that the following products:

1	B88-100FRT	Aerobic complex Real-TM Quant Real Time Amplification kit	CE
2	B45-50FRT	A.I.I. Screen Real-TM Real Time Amplification kit	CE
3	V57-100FRT TV57-100FRT	ARVI Screen Real-TM Real Time PCR kit	CE
4	R-V33-FRT TR-V33-FRT	Avian A Screening & H5N1 Typing FRT Real Time Amplification kit	CE
5	B101-50FRT	Bacillus anthracis Real-TM Real Time PCR kit	CE
6	B74-100FRT TB74-100FRT	Bacterial vaginosis Real-TM Quant Real Time PCR kit	CE
7	R-O1 TR-O1	BCR-ABL M-bcr Real-TM Quant Real Time PCR kit	CE
8	B84-100FRT	Bordetella pertussis/B.parapertussis/B.bronchiseptica Real-TM Real Time Amplification kit	CE
9	B37-50FRT	Borrelia burgdorferi Real-TM Real Time Amplification kit	CE
10	H2842-50FRT	Borrelia miyamotoi Real-TM Real Time Amplification kit	CE
11	B10-50FRT	Brucella Real-TM Real Time PCR kit	CE
12	F3-100FRT TF3-100FRT	Candida albicans/Candida glabrata/Candida krusei Real-TM Real Time PCR kit	CE
13	B35-50FRT	Campylobacter species Real-TM Real Time Amplification kit	CE
14	F1-100FRT TF1-100FRT	Candida albicans Real-TM Real Time PCR kit	CE
15	F5-100FRT TF5-100FRT	Candidosis Real-TM Quant Real Time PCR kit	CE
16	V122-96FRT	Chikungunya Real-TM Real Time PCR kit	CE
17	B1-100FRT	Chlamydia trachomatis Real-TM Real Time PCR kit	CE 1023
18	B60-100FRT	Chlamydia trachomatis/Ureaplasma/M.genitalium/M.hominis Real-TM Real Time PCR kit	CE 1023
19	B43-100FRT	Chlamydia trachomatis/Ureaplasma/M.hominis Real-TM Real Time PCR kit	CE 1023
20	V7-100FRT	CMV Real-TM Real Time PCR kit	CE 1023
21	V7-100/2FRT	CMV Real-TM Quant Real Time PCR kit	CE 1023
22	V22-50FRT	Congo Crimea Real-TM Real Time Amplification kit	CE
23	B2842-100FRT	Corynebacterium diphtheriae / tox genes Real-TM Real Time Amplification kit	CE
24	B85-50FRT	Coxiella burnetii Real-TM Real Time Amplification kit	CE
25	B58-50FRT	Cronobacter sakazakii Real-TM Real Time Amplification kit	CE
26	F4-100FRT	Cryptococcus neoformans Real-TM Real Time PCR kit	CE
27	V63-50FRT	Dengue Real-TM genotype Real Time PCR kit	CE
28	V63-S-50FRT	Dengue Real-TM Real Time PCR kit	CE

29	K-1-1/A K-1-1/A100	DNA-Sorb-A DNA Extraction kit	CE
30	K-1-1/B K-1-1/B100	DNA-Sorb-B DNA Extraction kit	CE
31	K-1-6/50	DNA-Sorb-C DNA Extraction kit	CE
32	K-2-9	DNA/RNA Prep DNA/RNA Extraction kit	CE
33	K-2-9/2	DNA/RNA Prep NA DNA/RNA Extraction kit	CE
34	V9-50FRT V9-100FRT TV9-100FRT	EBV Real-TM Quant Real Time PCR kit	CE
35	V48-100FRT	CMV/EBV/HHV6 Quant Real-TM Real Time PCR kit	CE 1023
36	B59-50FRT	EHEC Real-TM Real Time Amplification kit	CE
37	V16-50FRT	Enterovirus Real-TM Real Time PCR kit	CE
38	V64-50FRT	Enterovirus 71-Type Real-TM Real Time PCR kit	CE
39	B62-50FRT	Escherichioses Screen & Diff Real-TM Real Time Amplification kit	CE
40	B7-100FRT TB7-100FRT	Gardnerella vaginalis Real-TM Real Time PCR kit	CE
41	R-B7-100FRT TR-B7-100FRT	Gardnerella vaginalis/Lactobacillus species Real-TM Quant Real Time PCR kit	CE
42	V4-50FRT TV4-50FRT C	HAV Real-TM Real Time PCR kit	CE
43	V5-96/3FRT	HBV Real-TM Quant DX Real Time PCR kit	CE 1023
44	V1-96/3FRT	HCV Real-TM Quant DX Real Time PCR kit	CE 1023
45	B9-50FRT	Helicobacter pylori Real-TM Real Time Amplification kit	CE
46	V10-100FRT TV10-100FRT	HHV6 Real-TM Quant Real Time PCR kit	CE
47	V0-96/3FRT	HIV Real-TM Quant DX Real Time PCR kit	CE 1023
48	H53-100FRT	HLA B*5701 Real-TM Real Time PCR kit	CE
49	R116-50FRT	HLA-B27 Real-TM Real Time PCR kit	CE
50	V67-100FRT	HPV genotypes 14 Real-TM Quant Real Time PCR kit	CE
51	V31-100/F FRT	HPV 14 Screening & 16, 18, 45 Typing Real-TM Quant Amplification and Agarose gel detection kit	CE
52	V31-100/2FRT TV31-100/2FRT	HPV High Risk Screen Real-TM Quant Real Time PCR kit	CE
53	V31-100/2FRT2x TV31-100/2FRT2x	HPV High Risk Screen Real-TM Quant 2X Real Time PCR kit	CE
54	V-25-50F	HPV High Risk Typing Amplification and Agarose gel detection kit	CE
55	V26-100F	HPV High Risk Screen Amplification and Agarose gel detection kit	CE
56	V12-100FRT TV12-100FRT	HPV 16/18 Real-TM Quant Real Time PCR kit	CE
57	V11-100FRT TV11-100FRT	HPV 6/11 Real-TM Real Time PCR kit	CE
58	V37-50FRT	hRSV Real-TM Real Time PCR kit	CE

59	V8-100FRT TV8-100FRT	HSV 1/2 Real-TM Real Time PCR kit	CE
60	V38-100FRT TV38-100FRT	HSV 1/2 Typing Real-TM Real Time PCR kit	CE
61	V60-100FRT	HSV/CMV Real-TM Real Time PCR kit	CE 1023
62	V36-100FRT	Influenza A, B Real-TM Real Time PCR kit	CE
63	V47-50FRT	Influenza A H5 H7 H9 Typing FRT Real Time PCR kit	CE
64	V54-50FRT	Influenza A H1N1 & H3N2 Real-TM Real Time PCR kit	CE
65	B50-50FRT	Legionella pneumophila Real-TM Real Time PCR kit	CE
66	N3-50FRT	Leishmania spp. Real-TM Real Time PCR kit	CE
67	B49-50FRT	Leptospira 16s RNA Real-TM Real Time PCR kit	CE
68	B14-50FRT	Listeria monocytogenes Real-TM Quant Real Time PCR kit	CE
69	K-2-16/1000	Magno-Virus Viral RNA/DNA Isolation kit	CE
70	C2-100FRT	MDR KPC/OXA Real-TM Real Time PCR kit	CE
71	C1-100FRT	MDR MBL (VIM,IMP,NDM) Real-TM Real Time PCR kit	CE
72	V65-50FRT	MERS-SARS CoV Real-TM Real Time PCR kit	CE
73	B78-100FRT	MRSA Quant Real-TM Real Time PCR kit	CE
74	B41-50FRT	MTB Diff Real-TM Real Time PCR kit	CE
75	B15-50FRT	MTB Real-TM Real Time PCR kit	CE
76	B4-100FRT TB4-100FRT	Mycoplasma genitalium Real-TM Real Time PCR kit	CE
77	B4-100FRT Q TB4-100FRT Q	Mycoplasma genitalium Real-TM Quant Real Time PCR kit	CE
78	B3-100FRT TB3-100FRT	Mycoplasma hominis Real-TM Real Time PCR kit	CE
79	B3-100FRT Q	Mycoplasma hominis Real-TM Quant Real Time PCR kit	CE
80	B5-100FRT TB5-100FRT	Neisseria gonorrhoeae Real-TM Real Time PCR kit	CE
81	B204-100FRT	Neisseria gonorrhoeae Real-TM Quant Real Time PCR kit	CE
82	B67-100FRT	N.gonorrhoeae/C. trachomatis//M.genitalium Real-TM Real Time PCR kit	CE 1023
83	B61-100FRT	N.gonorrhoeae/C.trachomatis/M.genitalium/T.vaginalis Real-TM Real Time PCR kit	CE 1023
84	B25-50FRT	NHS Meningitidis Real-TM Real Time PCR kit	CE
85	V51-50FRT	Parainfluenza Virus Real-TM Real Time PCR kit	CE
86	V49-50FRT	Parvovirus B19 Real-TM Quant Real Time PCR kit	CE
87	P2-50FRT	Pneumocystis jirovecii (carinii) Real-TM Real Time PCR kit	CE

88	V58-50FRT	Poliovirus Real-TM Real Time PCR kit	CE
89	B76-50FRT	Pseudomonas aeruginosa Real-TM Quant Real Time PCR kit	CE
90	K-2/C K-2/C/P K-2/C 100 K-2/C/P 100	Ribo-Virus RNA/DNA Column Extraction kit	CE
91	K-2-1 K-2-1/100	Ribo-Sorb RNA/DNA Extraction kit	CE
92	H2741-50FRT	Rickettsia conorii Real-TM Real Time PCR kit	CE
93	V40-50FRT	Rotavirus/Norovirus/Astrovirus Real-TM Real Time PCR kit	CE
94	V24-50FRT	Rubella Real-TM Qual Real Time PCR kit	CE 1023
95	SC-96I SC-96R	SaCycler-96 Real Time PCR System	CE
96	B11-50FRT	Salmonella spp Real-TM Real Time PCR kit	CE
97	SM003	SaMag Viral Nucleic Acid Extraction Kit RNA/DNA Purification kit	CE
98	SM007	SaMag STD DNA Extraction Kit DNA Purification kit	CE
99	SM006	SaMag Bacterial DNA Extraction Kit DNA Purification kit	CE
100	SM008	SaMag TB DNA Extraction Kit DNA Purification kit	CE
101	SM004	SaMag Tissue DNA Extraction Kit DNA Purification kit	CE
102	SM001	SaMag Blood DNA Extraction Kit DNA Purification kit	CE
103	SM009	SaMag FFPE DNA Extraction Kit DNA Purification kit	CE
104	SM015	SaMag Total RNA/DNA Extraction Kit DNA Purification kit	CE
105	SM-12	SaMag 12 Automatic Nucleic Acids Extraction System	CE
106	SM-24	SaMag 24 Automatic Nucleic Acids Extraction System	CE
107	B12-50FRT	Shigella spp & EIEC Real-TM Real Time PCR kit	CE
108	B44-50FRT	Shigella/Salmonella/Campylobacter Real-TM Real Time PCR kit	CE
109	B77-100FRT	Strep B Real-TM Quant Real Time PCR kit	CE
110	B82-100FRT	Streptococcus pyogenes Real-TM Quant Real Time PCR kit	CE
111	B77-100FRT TB77-100FRT	Strep B Real-TM Quant Real Time PCR kit	CE
112	V55-50FRT	Swine Influenza Virus A/H1 Real-TM Real Time PCR kit	CE
113	B65-100FRT TB65-100FRT	T. vaginalis/N. gonorrhoeae Real-TM Real Time PCR kit	CE
114	V59-100FRT	TBEV, B. burdgoferi, A. phagocytophilum, E. chaffeensis/E. muris Real-TM Real Time PCR kit	CE

115	P1-50FRT	Toxoplasma gondii Real-TM Real Time PCR kit	CE 1023
116	B20-100FRT TB20-100FRT	Treponema pallidum Real-TM Real Time PCR kit	CE
117	B6-100FRT TB6-100FRT	Trichomonas vaginalis Real-TM Real Time PCR kit	CE
118	B19-100FRT Q	Ureaplasma parvum/urealyticum Real-TM Quant Real Time PCR kit	CE
119	B19-100FRT TB19-100FRT	Ureaplasma parvum/urealyticum Real-TM Real Time PCR kit	CE
120	B75-100FRT Q	Ureaplasma parvum/Ur. Urealyticum/M.hominis Quant Real-TM Real Time PCR kit	CE
121	B2-100FRT TB2-100FRT	Ureaplasma species Real-TM Real Time PCR kit	CE
122	B2-100FRTQ TB2-100FRTQ	Ureaplasma species Real-TM Quant Real Time PCR kit	CE
123	V61-50FRT	VZV Real-TM Real Time PCR kit	CE
124	V53-50FRT	West Nile Virus Real-TM Real Time PCR kit	CE
125	B64-50FRT	Yersinia enterocolitica/Y. pseudotuberculosis Real-TM Real Time PCR kit	CE
126	B79-50FRT	Yersinia pestis Real-TM Real Time PCR kit	CE
127	B46-100FRT	Chlamydia trachomatis/Ureaplasma/M.genitalium Real-TM Real Time PCR kit	CE 1023
128	T01101-50-T T01101-96-S	FV (G1691A) Leiden SNP-Screen Real Time PCR kit	CE
129	T01102-50-T T01102-96-S	FII Protrombin (G20210A) SNP-Screen Real Time PCR kit	CE
130	T01103-50-T T01103-96-S	MTHFR (C677T) SNP-Screen Real Time PCR kit	CE
131	R-05-100FRT	IL28B RS17/RS60 Real-TM Real Time PCR kit	CE
132	V2-50FRT	HGV Real-TM Real Time PCR kit	CE
133	B83-100FRT	T. vaginalis/N. gonorrhoeae/C. trachomatis Real-TM Real Time PCR kit	CE 1023
134	B42-4-50FRT B42-4-100FRT	Mycoplasma pneumoniae/Chlamydia pneumoniae Real-TM Real Time PCR kit	CE 1023
135	V71-100FRT	JCV/BKV Virus Real-TM Real Time PCR kit	CE
136	V73-50FRT	Zika Virus Real-TM Real Time PCR kit	CE
137	B87-100FRT TB87-100FRT	HSV1/HSVII/T. pallidum Real-TM Real Time PCR kit	CE
138	T01707-96-S T01707-96-S/L	PeriodontScreen Real-TM Real Time PCR kit	CE
139	V435-100FRT	SARS-CoV-2 Real-TM Real Time PCR kit	CE

fabbricato dalla ditta SACACE BIOTECHNOLOGIES srl, ai sensi dell'Allegato IV – sezione 3.2 della Direttiva 98/79/CE, recepita in Italia con L. 331 del 7.12.1998, sono conformi ai Requisiti Essenziali di cui all'Allegato I della:

manufactured by SACACE BIOTECHNOLOGIES srl, according to Annex IV – section 3.2 of Directive 98/79/CE, implemented by Italian Government with L. 331 dated 7.12.1998, are in compliance with the Essential Requirements (Annex I) of the:

Direttiva 98/79/CE Directive 98/79/EC

e delle seguenti norme tecniche:

as well as of the following technical standards:

UNI CEI EN 1041:2013	Informazioni fornite dal fabbricante di dispositivi medici Information supplied by the manufacturer of the medical devices
UNI EN ISO 18113-1:2012	Dispositivi medico-diagnostici in vitro - Informazioni fornite dal fabbricante (etichettatura) - Parte 1: Termini, definizioni e requisiti generali In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
UNI EN ISO 18113-2:2012	Dispositivi medico-diagnostici in vitro - Informazioni fornite dal fabbricante (etichettatura) - Parte 2: Reagenti diagnostici in vitro per uso professionale In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
UNI CEI EN ISO 14971: 2012	Dispositivi medici - Applicazione della gestione dei rischi ai dispositivi medici Medical devices - Application of risk management to medical devices
UNI CEI EN ISO 15223-1:2017	Dispositivi medici - Simboli da utilizzare nelle etichette del dispositivo medico, nell'etichettatura e nelle informazioni che devono essere fornite – Parte 1: Requisiti generali Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
UNI EN ISO 23640:2015	Dispositivi medico-diagnostici in vitro – Valutazione della Stabilità dei reagenti diagnostici in vitro In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents

La scrivente SACACE BIOTECHNOLOGIES srl, con la presente dichiarazione, si impegna a conservare e tenere a disposizione dell'Autorità Competente la documentazione tecnica di prodotto per un periodo minimo di 5 anni;

The Company SACACE BIOTECHNOLOGIES srl, with this Declaration, undertakes to keep and to put at the Competent Authority disposal all the product technical documentation related to the products for at least 5 years.

Como, 15/05/2020

Sacace Biotechnologies S.r.l.

L'AMMINISTRATORE UNICO

Dott. Alexander Safoian



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