



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

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

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

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

115	P1-50FRT	<b>Toxoplasma gondii Real-TM</b> Real Time PCR kit	CE 1023
116	B20-100FRT TB20-100FRT	<b>Treponema pallidum Real-TM</b> Real Time PCR kit	CE
117	B6-100FRT TB6-100FRT	<b>Trichomonas vaginalis Real-TM</b> Real Time PCR kit	CE
118	B19-100FRT Q	<b>Ureaplasma parvum/urealyticum Real-TM Quant</b> Real Time PCR kit	CE
119	B19-100FRT TB19-100FRT	<b>Ureaplasma parvum/urealyticum Real-TM</b> Real Time PCR kit	CE
120	B75-100FRT Q	<b>Ureaplasma parvum/Ur. Urealyticum/M.hominis Quant Real-TM</b> Real Time PCR kit	CE
121	B2-100FRT TB2-100FRT	<b>Ureaplasma species Real-TM</b> Real Time PCR kit	CE
122	B2-100FRTQ TB2-100FRTQ	<b>Ureaplasma species Real-TM Quant</b> Real Time PCR kit	CE
123	V61-50FRT	<b>VZV Real-TM</b> Real Time PCR kit	CE
124	V53-50FRT	<b>West Nile Virus Real-TM</b> Real Time PCR kit	CE
125	B64-50FRT	<b>Yersinia enterocolitica/Y. pseudotuberculosis Real-TM</b> Real Time PCR kit	CE
126	B79-50FRT	<b>Yersinia pestis Real-TM</b> Real Time PCR kit	CE
127	B46-100FRT	<b>Chlamydia trachomatis/Ureaplasma/M.genitalium Real-TM</b> Real Time PCR kit	CE 1023
128	T01101-50-T T01101-96-S	<b>FV (G1691A) Leiden SNP-Screen</b> Real Time PCR kit	CE
129	T01102-50-T T01102-96-S	<b>FII Protrombin (G20210A) SNP-Screen</b> Real Time PCR kit	CE
130	T01103-50-T T01103-96-S	<b>MTHFR (C677T) SNP-Screen</b> Real Time PCR kit	CE
131	R-05-100FRT	<b>IL28B RS17/RS60 Real-TM</b> Real Time PCR kit	CE
132	V2-50FRT	<b>HGV Real-TM</b> Real Time PCR kit	CE
133	B83-100FRT	<b>T. vaginalis/N. gonorrhoeae/C. trachomatis Real-TM</b> Real Time PCR kit	CE 1023
134	B42-4-50FRT B42-4-100FRT	<b>Mycoplasma pneumoniae/Chlamydophila pneumoniae Real-TM</b> Real Time PCR kit	CE 1023
135	V71-100FRT	<b>JCV/BKV Virus Real-TM</b> Real Time PCR kit	CE
136	V73-50FRT	<b>Zika Virus Real-TM</b> Real Time PCR kit	CE
137	B87-100FRT TB87-100FRT	<b>HSV1/HSVII/T. pallidum Real-TM</b> Real Time PCR kit	CE
138	T01707-96-S T01707-96-S/L	<b>PeriodontScreen Real-TM</b> Real Time PCR kit	CE
139	V435-100FRT	<b>SARS-CoV-2 Real-TM</b> Real Time PCR kit	CE
140	K-1-1/E	<b>Genomic Column DNA Express</b> DNA Extraction 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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