

DICHIARAZIONE DI CONFORMITA'

DECLARATION OF CONFORMITY

Fabbricante: SCREEN Italia s.r.l., via Volumnia 40/B, 06135 Ponte San Giovanni (Perugia)

Manufacturer: SCREEN Italia s.r.l., via Volumnia 40/B, 06135 Ponte San Giovanni (Perugia)

Tipologia prodotti: droga test e altri

Product type: drug test and others

Classificazione: altri dispositivi (dispositivi non contenuti nell'Allegato II e non self-testing)

Classification: other device (all device except Annex II and self testing devices)

Con la presente dichiariamo che la tipologia di prodotti sopra indicati, riportati nell'Allegato I, soddisfano le disposizioni della direttiva 98/79/CE per i dispositivi medici diagnostici in vitro. Tutta la documentazione di supporto è conservata sotto la responsabilità del fabbricante.

We herewith declare that above mentioned product, listed in Annex I, meet the provisions of the council directive 98/79/EC for in vitro medical devices. All supporting documentation is retained under the premises of the manufacturer.

SCREEN Italia considera le seguenti regole e norme:

SCREEN Italia considers following rules and standards:

- UNI CEI EN ISO 14971:2012 - Dispositivi medici - Applicazione della gestione dei rischi ai dispositivi medici
- *UNI CEI EN ISO 14971:2012 - Medical devices. Application of risk management to medical devices*
- UNI CEI EN ISO 13485:2012 - Dispositivi medici - Sistemi di gestione per la qualità - Requisiti per scopi regolamentari
- *UNI CEI EN ISO 13485:2012 - Medical devices -- Quality management systems -- Requirements for regulatory purposes*
- *UNI EN ISO 18113-1:2012 – Dispositivi medico diagnostici in-vitro - Informazioni fornite dal fabbricante (etichettatura) – Parte 1: Termini, definizioni e requisiti generali.*
- *UNI EN ISO 18113-1:2012 - 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*
- *UNI EN ISO 18113-2:2012: In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 2: In vitro diagnostic reagents for professional use*
- UNI CEI EN ISO 15223-1:2012 - Dispositivi medici - Simboli da utilizzare nelle etichette del dispositivo medico, nell'etichettatura e nelle informazioni che devono essere fornite - Parte 1: Requisiti generali
- *UNI CEI EN ISO 15223-1:2012 - Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements*

Perugia, 10 ottobre 2017

Perugia, October 10th, 2017



SCREEN ITALIA SRL

Allegato 1: Elenco in vitro medical device

Annex 1: in vitro medical device list

Nome prodotto <i>Product name</i>	Droga <i>Drug</i>	Codice prodotto <i>Product code</i>	Classe di rischio <i>Risk class</i>	Codice EDMS <i>EDMS Code</i>
SCREEN 7 + AD Screen Multi Dip-line 7+AD	AMP500/COC/MDMA500/MET500/MOR/ MTD/THC WITH pH AND CREATININE	DUA-174	Low Risk	120901900
SCREEN 8 + AD Screen Multi Dip-line 8+AD	AMP500/BUP/COC/MDMA500/MET500/ MOR/MTD/THC WITH pH AND CREATININE	DUA-184	Low Risk	120901900
SCREEN CUP 8 + A + AD Screen Cup 8+A+AD	AMP/COC/MDMA/MET/MTD/OPI/THC+ BUP/ALC/pH,SG,OX/CR,NI,GL	DUA-187-b	Low Risk	120901900
SCREEN K2/SPICE Screen Test K2/Spice	Marijuana Sintetica (K2)	DSM-114	Low Risk	120901500
SCREEN 8 Screen Multi Line 8	AMP500/COC)+(MET500/MOR)+ (MDMA500/MTD)+(BUP)+(THC)	DOA-185-S	Low Risk	120901900
SCREEN 10 Screen Multi Line 10	(AMP1000/COC/THC)+(MET500/MOR)+ (BZO/BAR)+(MDMA500/MTD)+(PCP)	DOA-1105-S1	Low Risk	120901900
SCREEN 10 Screen Multi Line 10	(AMP500/COC/THC)+(MET500/MOR)+ (BZO/TCA)+(MDMA500/MTD)+ (BUP)	DOA-1105-S2	Low Risk	120901900
SCREEN K2-S/SPICE Screen Test K2-S/Spice Saliva	Marijuana Sintetica (K2)	DSM-815	Low Risk	120901050
SCREEN PH TEST Test del Ph Vaginale	pH vaginale	IVPH-504	Low Risk	110402020
ETIL PROFESSIONAL Alcol Test Saliva	Ethanol (Alcohol)	DAL-701-C	Low Risk	120902070
SCREEN 8 Screen Multiline 8	AMP500/COC)+(MET500/MOR)+ (MDMA500/MTD)+(BUP5)+(THC)	DOA-185-P	Low Risk	120901900
SCREEN 8+AD Screen Multi Dip-line 8+AD	AMP500/BUP5/COC/MDMA500/MET500/ MOR/MTD/THC WITH pH AND CREATININE	DUA-184-P	Low Risk	120901900
SCREEN 6-S Drug Test Saliva 6	OPI/COC/THC/AMP MDMA/MTD	DSD-865	Low Risk	120901900

SCREEN ALCOL TEST ETG Alcol Test Urine ETG	Alcol Test Urine ETG	DET-114	Low Risk	11.70.02.90
SCREEN FLU TEST Test Influenza A/B	Test Influenza A/B	IIN-502	Low Risk	15.04.80.04
SCREEN STREP A TEST Test Streptococco	Group A streptococcus device test	IST-502	Low Risk	14.02.03.02
SCREEN TETAN TEST Test Tetano	Tetanus test	ITE- 402	Low Risk	15.01.90.09
SCREEN FAMILY SPERM Test Fertilità Maschile	Test fertilità	OSC-902	Low Risk	12.05.01.90
SCREEN H. PYLORI ANTIBODY Test H.Pylori	Test H.Pylori Antibody	IHP-402	Low Risk	15.01.04.03
SCREEN H. PYLORI ANTIGEN Test H.Pylori	Test H.Pylori Antigen	IHP-602	Low Risk	15.01.04.01
SCREEN MONO Test Mononucleosi	Test Mononucleosi	IMO-402	Low Risk	15.70.90.03
SCREEN ROTAVIRUS Test Rotavirus	Test Rotavirus	IRO-602	Low Risk	15.04.80.06
SCREEN ADENOVIRUS Test Adenovirus	Test Adenovirus	IAD-602	Low Risk	15.04.80.01
SCREEN CMV IGM Test CMV Igm	Test CMV Igm	ICM-302	Low Risk	15.04.02.06
SCREEN OFD Oral fluid drug screen device	COC/MET/PCP/THC OPI/AMP	DSB-765	Low Risk	1209019000
SCREEN GONORRHEA Test Gonorrea	Test Gonorrea	IGO-502	Low Risk	15.01.02.01
SCREEN HSV 1/2 IGM Test HSV ½ Igm	Test HSV1/2 Igm	ISM-302	Low Risk	15.04.03.06
SCREEN NICOTINA-S Test Nicotina Saliva	Test Cotinina	DCT-802	Low Risk	12.09.01.08
SCREEN NICOTINA Test Nicotina Urina	Test Cotinina	DCT-114	Low Risk	12.09.01.08

SCREEN 5 One Step Drug Test Card	COC300-AMP1000-MET1000-OPI2000-THC50	DOA-154-C	Low Risk	12.09.01.90
SCREEN GENERIC TEST URINA 12 Generic Test Urina	Test Urina	URS-12MA:11MA	Low Risk	11.70.02.90
SCREEN READER Lettore Test Rapidi	Strumento di Stampa	SCREEN0016	Low Risk	29.01.10.01
SCREEN MALARIA – P.F./P.V. Test Malaria	Test Malaria P.F./P.V.	IMPV-402	Low Risk	15.05.10.09
SCREEN SYPHILIS Test Sifilide	Test Syphilis	ISY-402	Low Risk	15.01.03.03
SCREEN TUBERCULOSIS Test Tuberculosi	Test Tuberculosis (Isotipi IgG, IgM e IgA)	ITB-402	Low Risk	13.05.02.02
SCREEN 12 Screen Multiline 12	(MDMA/MTD/MOP) + (MET/COC/THC) + (OXY/BZO/K2) + (KET/TML) + BUP	DOA-1125	Low Risk	12.09.01.90
SCREEN 10 One Step drug test card	MOP/COC/THC/AMP500/MET500/ MTD/BAR/BZD/TCA/BUP	DOA-1104	Low Risk	12.09.01.90
SCREEN 9 Screen Multiline 9	AMP500/COC+BAR/MOR+MDMA500/MTD +TCA/BZO+THC	DOA-195-S	Low Risk	12.09.01.90
SCREEN CRP TEST Test C-reactive protein	C-reactive protein rapid test	CCR-402	Low Risk	12.70.13.90
SCREEN 1 One step drug test card	Amphetamine	DAM-114	Low Risk	1209010100
SCREEN 1 One step drug test card	Barbiturates	DBA-114	Low Risk	1209010300
SCREEN 1 One step drug test card	Benzodiazepine	DBZ-114	Low Risk	1209010400
SCREEN 1 One step drug test card	Cocaine	DCO-114	Low Risk	1209010600
SCREEN 1 One step drug test card	Ketamine	DKE-114	Low Risk	1209019000
SCREEN 1 One step drug test card	Methamphetamine	DMA-114	Low Risk	1209010200

SCREEN 1 One step drug test card	Ecstasy	DMD-114	Low Risk	1209010200
SCREEN 1 One step drug test card	Opiates	DOP-114	Low Risk	1209011300
SCREEN 1 One step drug test card	Marijuana	DTH-114	Low Risk	1209010500
SCREEN 1 One step drug test card	Buprenorphine	DBU-114	Low Risk	1209019000
SCREEN 1 One step drug test card	Methadone	DMT-114	Low Risk	1209011000
SCREEN 5 One step drug test card	COC/AMP/MET/THC/OPI	DOA-154	Low Risk	1209019000
SCREEN 7 One step drug test card	COC/AMP500/MET500 THC/MTD/MDMA/MOP	DOA-174	Low Risk	1209019000
SCREEN 8 One step drug test card	COC/AMP/THC/MTD MOP/BAR/BZO/TCA	DOA-184	Low Risk	1209019000
SCREEN 8 +AD One step drug test card	COC/AMP500/MET500 THC/MOP/MDMA/MTD BUP/CREATINE/PH	DUD-184	Low Risk	1209019000
SCREEN 10 One step drug test card	COC/AMP/MET/THC MTD/OPI/BUP/BAR BZO/TCA	DOA-110 (B)	Low Risk	1209019000
SCREEN 10 One step drug test card	COC/AMP/MET/THC MTD/OPI/PCP/BAR BZO/TCA	DOA-1104(P)	Low Risk	1209019000
SCREEN FOB TEST Test FOB	Faecal Occult Blood	TFO-602	Low Risk	11.70.03.01
SCREEN MIOGLOB./TROPON./CK-MB Test myoglobin/troponin i/ck-mb combo	Other Cardiac Marker Rapid Tests	CMA-435	Low Risk	12.70.13.90
SCREEN GENERIC TEST URINA 11 Generic Test Urina	TEST URINA	U031-11	Low Risk	11.70.02.02
SCREEN 8 +AD Screen Multi Dip-Line 8+AD	AMP500/BUP/COC/MDMA500 MET500/MOR/MTD/THC pH AND CREATININE	SDUA-184	Low Risk	12.09.01.90

SCREEN CUP 8+AD Screen Cup 8 +AD	COC/AMP500ng/MET500ng/THC MOP/MDMA/MTD/BUP pH AND CREATININE	SDOA-184	Low Risk	12.09.01.90
SCREEN 7+AD Screen Multi Dip-Line 7+AD	AMP500/COC/MDMA500/MET500 MOR/MTD/THC pH AND CREATININE	SDUA-174	Low Risk	12.09.01.90
SCREEN 6-S2 Drug test saliva 6	OPI/COC/THC/OXY/AMP/MAMP-MDMA	DSD-865-A	Low Risk	12.09.01.90
SCREEN CUBE 7-S Drug test oral fluid	AMP 40/COC 30/MDMA 50/MAMP 40/ OPI 40/OXY 40/THC 25	SC-274	Low Risk	12.09.01.90
SCREEN MIDSTREAM 6-S Drug test oral fluid	OPI 40/COC 30/THC 25/AMP 40/MET 40-MDMA 50/OXY 40	DSD-863-A	Low Risk	12.09.01.90
SCREEN MIDSTREAM 6-S4 Drug Test Oral Fluid	OPI/COC/THC/AMP/ MET-MDMA/MTD	DSD-863-D	Low Risk	12.09.01.90
SCREEN MIDSTREAM 6-S3 Drug Test Oral Fluid	OPI/COC/THC/AMP/ MET-MDMA/BZO	DSD-863-C	Low Risk	12.09.01.90
SCREEN MIDSTREAM 6-S2 Drug Test Oral Fluid	OPI/COC/THC/AMP/ MET-MDMA/SMA-K2	DSD-863-B	Low Risk	12.09.01.90
SCREEN GENERIC TEST URINA 10 Generic Test Urina	Test Urina	U031-10	Low Risk	11.70.02.02
SCREEN MIDSTREAM 6-S-MED Drug Test Oral Fluid	OPI 40/COC 30/AMP 40/MET 40/MDMA 50/THC 10	DSD-863-M	Low Risk	12.09.01.90
SCREEN TEST ADULTERAZIONE Screen Adulteration strips	Creatinina, Nitriti, Glutaraldeide, pH, Peso Specifico e Ossidanti/Clorocromato di piridinio (PCC)	SCR0011	Low Risk	11.70.02.02
SCREEN CUP 10 + A + AD Screen Cup 10+A+AD	AMP-BAR-BUP-BZO-COC-MDMA-MTD-OPI- PCP-THC-ALCOL+PH,SG,OX,CR,NI,GL	DUA-1107-A2	Low Risk	12.09.01.90
SCREEN CUP 10 + A + AD Screen Cup 10+A+AD	AMP-MET-BAR-BUP-BZO-COC-MTD-OPI- KET-THC-ALCOL+PH,SG,OX,CR,NI,GL	DUA-1107-A3	Low Risk	12.09.01.90
SCREEN CUP 12 + A + AD Screen Cup 12+A+AD	BAR-BUP-BZO-COC-MDMA-MET-MTD-OPI- OXY-PCP-PPX-THC-ALCOL+PH,SG,OX	DUA-1127-A2	Low Risk	12.09.01.90
SCREEN CUP 12 + A + AD Screen Cup 12+A+AD	BAR-BUP-BZO-COC-AMP-MET-MTD-OPI- OXY-KET-PPX-THC-ALCOL+PH,SG,OX	DUA-1127-A3	Low Risk	12.09.01.90
SCREEN CUP 10-S Oral Fluid Drug Test	AMP-MET-MDMA-KET-COC-MTD-OPI-THC- K2-ALC	DOA- OC1-10	Low Risk	12.09.01.90

SCREEN ANALYSIS METER 10 Urine Analysis Meter	LETTORE TEST 10 PARAMETRI	URM-100	Low Risk	24.06.10.01
SCREEN ANALYSIS METER 11 Urine Analysis Meter	LETTORE TEST 11 PARAMETRI	URM-110	Low Risk	24.06.10.01
SCREEN ANALYSIS METER 12 Urine Analysis Meter	LETTORE TEST 12 PARAMETRI	URM-200	Low Risk	24.06.10.01
SCREEN PROCALCITONINA TEST Test Procalcitonina	Procalcitonin (PCT) Rapid Test	CPC-402	Low Risk	12.06.90.16
SCREEN CUP 8+AD Screen Cup 8+AD	COC/AMP500ng/MET500ng/THC/MOP/MD MA/MTD/BUP WITH pH AND CREATININE	DUA-1108-A2	Low Risk	12.09.01.90
SCREEN MYCOPLASMA TEST Test Mycoplasma	Mycoplasma Pneumoniae Antigen Rapid Test	IMP-502	Low Risk	15.01.08.01
SCREEN CUP 7+AD Screen Cup 7 +AD	COC/AMP500ng/MET500ng/THC/MOP/MD MA/MTD WITH pH AND CREATININE	DUA-167-B	Low Risk	12.09.01.90
SCREEN CALPROTECTINA Calprotectin Rapid Test Cassette	Calprotectin	OCAL-602	Low Risk	12.01.90.10
SCREEN CLOSTRIDIUM Clostridium difficile Rapid Test Cassette	Clostridium	ICD-602	Low Risk	15.01.90.02
SCREEN HCG TEST Pregnancy Rapid Test Cassette	Human Chorionic Gonadotropin	FHC-102	Low Risk	12.05.02.05
SCREEN NOROVIRUS Norovirus Rapid Test Cassette	Norovirus	INO-602	Low Risk	15.04.80.16
SCREEN HCG TEST Pregnancy Rapid Test H/S Cassette	Human Chorionic Gonadotropin	FHC-U102	Low Risk	12.05.02.05
SCREEN 10 SCREEN MULTILINE 10	BUP, PCP, TCA, TML, KET 300, EDDP 300, FYL 10, K2 30, PPX, OXY	DOA-1105-S3	Low Risk	12.09.01.90
SCREEN 5 SCREEN MULTILINE 5	OXY100/EDDP300/PCP25/TML100/K2-30	DOA-155-S1	Low Risk	12.09.01.90
SCREEN 5 SCREEN MULTILINE 5	PPX300/KET300/FYL10/TCA1000/BUP10	DOA-155-S2	Low Risk	12.09.01.90
SCREEN CLOSTRIDIUM A+B	Clostridium difficile Rapid Toxin A+Toxin B	ICDT-625	Low Risk	15.01.90.02
SCREEN 12 One step drug test card	MOP300/MDMA500/OXY100/PCP25/COC3 00/MTD300/BAR300/BZO300/AMP1000/M ET500/TCA1000/THC50	DOA-1124	Low Risk	12.09.01.90

SCREEN CUP 7+ADU Screen Cup 7 + ADU	COC/AMP500ng/MET500ng/THC/MOP/MD MA/MTD WITH OX, S.G., PH, NIT, GLUT e CRE	DUA-167-B2	Low Risk	12.09.01.90
SCREEN CHIKUNGUNYA TEST Test Chikungunya	Test Chikungunya	ICHI-402	Low Risk	15.04.80.25
SCREEN ZIKA TEST Test Zika	Test Zika	IZIG-402	Low Risk	15.70.90.90