

DICHIARAZIONE DI CONFORMITA'

DECLARATION OF CONFORMITY

Fabbricante: SCREEN ITALIA s.r.l. via dell'Artigianato, 16 - 06089 - Torgiano - (Perugia)

Manufacturer: SCREEN ITALIA s.r.l. via dell'Artigianato, 16 - 06089 - Torgiano - (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 14971:2019 - 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 13485:2016 - Dispositivi medici - Sistemi di gestione per la qualità - Requisiti per scopi regolamentari
- *UNI CEI EN ISO 13485:2016 - 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*

Torgiano, 12 Novembre 2020

Torgiano, November 12th 2020

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Codice Univoco: USAL8PV

SCREEN ITALIA SRL

Allegato 1: Elenco in vitro medical device

Annex 1: in vitro medical device list

Nome prodotto <i>Product name</i>	Descrizione <i>Description</i>	Codice prodotto <i>Product code</i>	Classe di rischio <i>Risk class</i>	Codice EDMS <i>EDMS Code</i>
SCREEN 7 + AD Multi Drug Rapid Test Panel	AMP500/COC/MDMA500/MET500/MOR/MTD/THC WITH pH AND CREATININE	DUA-174	Low Risk	12.09.01.90
SCREEN 8 + AD Multi Drug Rapid Test Panel	AMP500/BUP/COC/MDMA500/MET500/MOR/MTD/THC WITH pH AND CREATININE	DUA-184	Low Risk	12.09.01.90
SCREEN CUP 8 + A + AD Multi Drug Rapid Test Cup	AMP/COC/MDMA/MET/MTD/OPI/THC+ BUP/ALC/pH,SG,OX/CR,NI,GL	DUA-187-b	Low Risk	12.09.01.90
SCREEN 1 One Step Drug Test Card	Marijuana Sintetica (K2)	DSM-114	Low Risk	12.09.01.05
SCREEN 8 Multi Line Drug Rapid Test Cassette	AMP500/COC)+(MET500/MOR)+ (MDMA500/MTD)+(BUP)+(THC)	DOA-185-S	Low Risk	12.09.01.90
SCREEN 10 Multi Line Drug Rapid Test Cassette	(AMP1000/COC/THC)+(MET500/MOR)+ (BZO/BAR)+(MDMA500/MTD)+(PCP)	DOA-1105-S1	Low Risk	12.09.01.90
SCREEN 10 Multi Line Drug Rapid Test Cassette	(AMP500/COC/THC)+(MET500/MOR)+ (BZO/TCA)+(MDMA500/MTD)+ (BUP)	DOA-1105-S2	Low Risk	12.09.01.90
SCREEN 1 K2-S Drug Rapid Test Oral Fluid	Marijuana Sintetica (K2)	DSM-815	Low Risk	12.09.01.05
SCREEN PH TEST Vaginal Ph Rapid Test	pH Vaginale	IVPH-504	Low Risk	11.04.02.02
ETIL PROFESSIONAL Saliva Alcohol Test	Ethanol (Alcohol)	DAL-701-C	Low Risk	12.09.02.07
SCREEN 8 Multi Line Drug Rapid Test Cassette	AMP500/COC)+(MET500/MOR)+ (MDMA500/MTD)+(BUP5)+(THC)	DOA-185-P	Low Risk	12.09.01.90
SCREEN 8+AD Multi Drug Rapid Test Panel	AMP500/BUP5/COC/MDMA500/MET500/ MOR/MTD/THC WITH pH AND CREATININE	DUA-184-P	Low Risk	12.09.01.90
SCREEN 6-S Multi Drug Rapid Test Oral Fluid	OPI/COC/THC/AMP MDMA/MTD	DSD-865	Low Risk	12.09.01.90
SCREEN ALCOL TEST ETG Ethyl Glucuronide (Etg) Rapid Test	Alcol Test Urine ETG	DET-114	Low Risk	11.70.02.90

SCREEN FLU TEST Influenza A+B Rapid Test	Test Influenza A/B	IIN-502	Low Risk	15.04.80.04
SCREEN STREP A TEST Strep A Rapid Test	Group A streptococcus device test	IST-502	Low Risk	14.02.03.02
SCREEN TETAN TEST Tetanus Rapid Test	Tetanus test	ITE- 402	Low Risk	15.01.90.09
SCREEN FAMILY SPERM Sperm Concentration Rapid Test	Test fertilità	OSC-902	Low Risk	12.05.01.90
SCREEN H. PYLORI ANTIBODY H.pylori Antibody Rapid Test	Test H.Pylori Antibody	IHP-402	Low Risk	15.01.04.03
SCREEN H. PYLORI ANTIGEN H.pylori Antigen Rapid Test	Test H.Pylori Antigen	IHP-602	Low Risk	15.01.04.01
SCREEN MONO TEST Mono Rapid Test	Test Mononucleosi	IMO-402	Low Risk	15.70.90.03
SCREEN ROTAVIRUS Rotavirus Rapid Test	Test Rotavirus	IRO-602	Low Risk	15.04.80.06
SCREEN ADENOVIRUS TEST Adenovirus Rapid Test Cassette	Test Adenovirus	IAD-602	Low Risk	15.04.80.01
SCREEN CMV IGM CMV IgM Rapid test Cassette	Test CMV Igm	ICM-302	Low Risk	15.04.02.06
SCREEN GONORRHEA Gonorrhea Rapid Test Cassette	Test Gonorrhea	IGO-502	Low Risk	15.01.02.01
SCREEN HSV 1/2 IGM HSV 1/2 IgM Rapid Test Cassette	Test HSV1/2 Igm	ISM-302	Low Risk	15.04.03.06
SCREEN NICOTINA-S COT Oral Fluid Test	Test Cotinina	DCT-802	Low Risk	12.09.01.08
SCREEN NICOTINA COT Rapid Test Cassette	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 Urinalysis Reagent Strips	Test Urina	URS- 12MA:11MA	Low Risk	11.70.02.90

SCREEN READER Rapid Test Reader	Strumento di Stampa	SCREEN0016	Low Risk	29.01.10.01
SCREEN MALARIA – P.F./P.V. Malaria P.F. /P.V. Rapid Test	Test Malaria P.F./P.V.	IMPV-402	Low Risk	15.05.10.09
SCREEN TEST SIFILIDE Syphilis Rapid Test	Test Syphilis	ISY-402	Low Risk	15.01.03.03
SCREEN TEST TUBERCULOSI Tuberculosis Rapid Test	Test Tuberculosis (Isotipi IgG, IgM e IgA)	ITB-402	Low Risk	13.05.02.02
SCREEN 12 Multi Line Drug Rapid Test Cassette	(MDMA/MTD/MOP) + (MET/COC/THC) + (OXY/BZO/K2) + (KET/TML) + BUP	DOA-1125	Low Risk	12.09.01.90
SCREEN 10 Multi Drug Rapid Test Panel	MOP/COC/THC/AMP500/MET500/ MTD/BAR/BZD/TCA/BUP	DOA-1104	Low Risk	12.09.01.90
SCREEN 9 Multi Line Drug Rapid Test Cassette	AMP500/COC+BAR/MOR+MDMA500/MTD +TCA/BZO+THC	DOA-195-S	Low Risk	12.09.01.90
SCREEN CRP TEST C-Reactive Protein Rapid Test	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	12.09.01.01
SCREEN 1 One step drug test card	Barbiturates	DBA-114	Low Risk	12.09.01.03
SCREEN 1 One step drug test card	Benzodiazepine	DBZ-114	Low Risk	12.09.01.04
SCREEN 1 One step drug test card	Cocaine	DCO-114	Low Risk	12.09.01.06
SCREEN 1 One step drug test card	Ketamine	DKE-114	Low Risk	12.09.01.90
SCREEN 1 One step drug test card	Methamphetamine	DMA-114	Low Risk	12.09.01.02
SCREEN 1 One step drug test card	Ecstasy	DMD-114	Low Risk	12.09.01.02
SCREEN 1 One step drug test card	Opiates	DOP-114	Low Risk	12.09.01.13

SCREEN 1 One step drug test card	Marijuana	DTH-114	Low Risk	12.09.01.05
SCREEN 1 One step drug test card	Buprenorphine	DBU-114	Low Risk	12.09.01.90
SCREEN 1 One step drug test card	Methadone	DMT-114	Low Risk	12.09.01.10
SCREEN 8 Multi Drug Rapid Test Panel	COC/AMP/THC/MTD MOP/BAR/BZO/TCA	DOA-184	Low Risk	12.09.01.90
SCREEN 10 Multi Drug Rapid Test Panel	COC/AMP/MET/THC MTD/OPI/PCP/BAR BZO/TCA	DOA-1104(P)	Low Risk	12.09.01.90
SCREEN FOB TEST FOB Rapid Test	Fecal Occult Blood	TFO-602	Low Risk	11.70.03.01
SCREEN MIOGLOB./TROPON./CK-MB Myoglobin/Troponin i/CK-MB Combo Test	Other Cardiac Marker Rapid Tests	CMA-435	Low Risk	12.70.13.90
SCREEN GENERIC TEST URINA 11 Urinalysis Reagent Strips	Test Urina	U031-11	Low Risk	11.70.02.02
SCREEN 8 +AD Multi Drug Rapid Test Panel	AMP500/BUP/COC/MDMA500 MET500/MOR/MTD/THC pH AND CREATININE	SDUA-184	Low Risk	12.09.01.90
SCREEN CUP 8+AD Multi Drug Rapid Test Cup	COC/AMP500ng/MET500ng/THC MOP/MDMA/MTD/BUP pH AND CREATININE	SDOA-184	Low Risk	12.09.01.90
SCREEN 7+AD Multi Drug Rapid Test Panel	AMP500/COC/MDMA500/MET500 MOR/MTD/THC pH AND CREATININE	SDUA-174	Low Risk	12.09.01.90
SCREEN 6-S2 Multi Drug Rapid Test Oral Fluid	OPI/COC/THC/OXY/AMP/MAMP-MDMA	DSD-865-A	Low Risk	12.09.01.90
SCREEN CUBE 7-S Multi Drug Rapid 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 Multi Drug Rapid 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 Multi Drug Rapid Test Oral Fluid	OPI/COC/THC/AMP/ MET-MDMA/MTD	DSD-863-D	Low Risk	12.09.01.90
SCREEN MIDSTREAM 6-S3 Multi Drug Rapid Test Oral Fluid	OPI/COC/THC/AMP/ MET-MDMA/BZO	DSD-863-C	Low Risk	12.09.01.90

SCREEN MIDSTREAM 6-S2 Multi Drug Rapid 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 Urinalysis Reagent Strips	Test Urina	U031-10	Low Risk	11.70.02.02
SCREEN MIDSTREAM 6-S-MED Multi Drug Rapid 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 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 Multi Drug Rapid Test Cup	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 Multi Drug Rapid Test Cup	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 Multi Drug Rapid Test Cup	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 Multi Drug Rapid Test Cup	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 Multi Drug Rapid Test Oral Fluid	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 Procalcitonin (PCT) Rapid Test	Procalcitonin (PCT) Rapid Test	CPC-402	Low Risk	12.06.90.16
SCREEN CUP 8+AD Multi Drug Rapid Test Cup	COC/AMP500ng/MET500ng/THC/MOP/MD MA/MTD/BUP WITH pH AND CREATININE	DUA-1108-A2	Low Risk	12.09.01.90
SCREEN TEST MYCOPLASMA Mycoplasma Pneumoniae Antigen Test	Mycoplasma Pneumoniae Antigen Rapid Test	IMP-502	Low Risk	15.01.08.01
SCREEN CUP 7+AD Multi Drug Rapid Test Cup	COC/AMP500ng/MET500ng/THC/MOP/MD MA/MTD WITH pH AND CREATININE	DUA-167-B	Low Risk	12.09.01.90
SCREEN TEST CALPROTECTINA Calprotectin Rapid Test Cassette	Calprotectin	OCAL-602	Low Risk	12.01.90.10

SCREEN CLOSTRIDIUM TEST Clostridium difficile GHD Rapid Test	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 TEST NOROVIRUS Norovirus Rapid Test	Norovirus	INO-602	Low Risk	15.04.80.16
SCREEN HCG TEST Pregnancy Rapid Test Cassette H/S	Human Chorionic Gonadotropin	FHC-U102	Low Risk	12.05.02.05
SCREEN 10 Multi Line Drug Rapid Test Cassette	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 Multi Line Drug Rapid Test Cassette	OXY100/EDDP300/PCP25/TML100/K2-30	DOA-155-S1	Low Risk	12.09.01.90
SCREEN 5 Multi Line Drug Rapid Test Cassette	PPX300/KET300/FYL10/TCA1000/BUP10	DOA-155-S2	Low Risk	12.09.01.90
SCREEN CLOSTRIDIUM A+B clostridium Difficile Toxin A+Toxin B	Clostridium difficile Rapid Toxin A+Toxin B	ICDT-625	Low Risk	15.01.90.02
SCREEN 12 Multi Drug Rapid Test Panel	MOP300/MDMA500/OXY100/PCP25/COC300/MTD300/BAR300/BZO300/AMP1000/MET500/TCA1000/THC50	DOA-1124	Low Risk	12.09.01.90
SCREEN CUP 7+ADU Multi Drug Rapid Test Cup	COC/AMP500ng/MET500ng/THC/MOP/MDMA/MTD WITH OX,S.G.,PH,NIT,GLUT e CRE	DUA-167-B2	Low Risk	12.09.01.90
SCREEN CHIKUNGUNYA TEST Chikungunya IGG/IGM Rapid Test	Test Chikungunya	ICHI-402	Low Risk	15.04.80.25
SCREEN ZIKA TEST NS1 Zika Rapid Test	Test Zika	IZIG-402	Low Risk	15.70.90.90
SCREEN TEST EPATITE A – HAV HAV IGM Rapid Test Cassette	Test Epatite A – Hav IgM	IHA-302	Low Risk	15.02.01.06
SCREEN TEST LEGIONELLA Legionella Pneumophila Rapid Test	Test Legionella	ILEG-102	Low Risk	15.01.05.01
SCREEN TEST VITAMINA D Vitamin D Rapid Test	Test Vitamina D	OVD-402	Low Risk	12.06.03.10
SCREEN TEST PNEUMOCOCCO S. Pneumoniae Antigen Test	Test Streptococcus pneumoniae	ISP-102	Low Risk	15.70.01.09
SCREEN CRYPTOSPORIDIUM Cryptosporidium Antigen Test	Cryptosporidium Antigen Rapid Test	ICR-602	Low Risk	14.05.02.03
SCREEN DENGUE COMBO Dengue Combo Rapid Test	Dengue Combo Rapid Test	IDEC-425	Low Risk	15.04.80.11

SCREEN DENGUE NS1 Dengue NS1 Rapid Test	Dengue NS1 Rapid Test	IDES-402	Low Risk	15.04.80.11
SCREEN GIARDIA LAMBLIA Giardia Lamblia Rapid Test	Giardia Lamblia Rapid Test	IGL-602	Low Risk	15.05.10.08
SCREEN CAMPYLOBACTER Campylobacter Rapid Test Cassette	Campylobacter Test Rapido a Cassetta	ICAM-602	Low Risk	15.01.14.01
SCREEN CLAMIDIA TEST Clamidia Rapid Test Cassette	Clamidia Test rapido a cassetta	ICH-502	Low Risk	15.01.01.01
SCREEN DRUG TEST CAPELLO Multi Drug Test Hair	Multi-Drug Rapid Test Cassette COT 0.2-MET 0.2-MOP 0.2-COC 0.5	DOA-945	Low Risk	12.70.09.70
SCREEN RUBELLA IGM Rubella IGM Rapid Test	Test Rapido Rosolia	IRM-302	Low Risk	15.04.01.06
SCREEN PSA TEST PSA Rapid Test	PSA Test rapido a cassetta	TPS-402	Low Risk	12.03.01.32
SCREEN TEST COVID-19 2019-ncov Igg/igm Rapid Test Cassette	Test Covid-19 2019-nCOV IgG/IgM Test Rapido a cassetta	INCP-402S	Low Risk	15.70.90.90
SCREEN TEST COVID-19 2019-ncov Igg/igm Rapid Test Dipstick	Test Covid-19 2019-nCOV IgG/IgM Test Rapido Dipstick	INCP-411A	Low Risk	15.70.90.90
SCREEN TEST COVID-19 2019-ncov Igg/igm Rapid Test Cassette	Test Covid-19 2019-nCOV IgG/IgM Test Rapido a cassetta	INCP-402B	Low Risk	15.70.90.90
SCREEN TEST COVID-19 AG Covid-19 Antigen Rapid Test	Covid-19 Antigen Rapid Test Test Rapido a cassetta	ICOV-502	Low Risk	15.70.90.90
SCREEN TEST COVID-19+FLU A/B Covid-19 And Influenza A+B Antigen Test	Covid-19 And Influenza A+B Antigen Test Test Rapido a cassetta	ICIC-525	Low Risk	15.70.90.90
SCREEN TEST COVID-19 SALIVA Covid-19 Antigen Rapid Test Oral Fluid	Test rapido Antigene Covid-19 (Fluido orale)	ICOV-802	Low Risk	15.70.90.90