

## **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 12<sup>th</sup> 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>
<b>SCREEN 7 + AD</b> Multi Drug Rapid Test Panel	AMP500/COC/MDMA500/MET500/MOR/MTD/THC WITH pH AND CREATININE	DUA-174	Low Risk	12.09.01.90
<b>SCREEN 8 + AD</b> 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
<b>SCREEN CUP 8 + A + AD</b> 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
<b>SCREEN 1</b> One Step Drug Test Card	Marijuana Sintetica (K2)	DSM-114	Low Risk	12.09.01.05
<b>SCREEN 8</b> Multi Line Drug Rapid Test Cassette	AMP500/COC)+(MET500/MOR)+ (MDMA500/MTD)+(BUP)+(THC)	DOA-185-S	Low Risk	12.09.01.90
<b>SCREEN 10</b> 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
<b>SCREEN 10</b> 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
<b>SCREEN 1 K2-S</b> Drug Rapid Test Oral Fluid	Marijuana Sintetica (K2)	DSM-815	Low Risk	12.09.01.05
<b>SCREEN PH TEST</b> Vaginal Ph Rapid Test	pH Vaginale	IVPH-504	Low Risk	11.04.02.02
<b>ETIL PROFESSIONAL</b> Saliva Alcohol Test	Ethanol (Alcohol)	DAL-701-C	Low Risk	12.09.02.07
<b>SCREEN 8</b> Multi Line Drug Rapid Test Cassette	AMP500/COC)+(MET500/MOR)+ (MDMA500/MTD)+(BUP5)+(THC)	DOA-185-P	Low Risk	12.09.01.90
<b>SCREEN 8+AD</b> 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
<b>SCREEN 6-S</b> Multi Drug Rapid Test Oral Fluid	OPI/COC/THC/AMP MDMA/MTD	DSD-865	Low Risk	12.09.01.90
<b>SCREEN ALCOL TEST ETG</b> Ethyl Glucuronide (Etg) Rapid Test	Alcol Test Urine ETG	DET-114	Low Risk	11.70.02.90

<b>SCREEN FLU TEST</b> Influenza A+B Rapid Test	Test Influenza A/B	IIN-502	Low Risk	15.04.80.04
<b>SCREEN STREP A TEST</b> Strep A Rapid Test	Group A streptococcus device test	IST-502	Low Risk	14.02.03.02
<b>SCREEN TETAN TEST</b> Tetanus Rapid Test	Tetanus test	ITE- 402	Low Risk	15.01.90.09
<b>SCREEN FAMILY SPERM</b> Sperm Concentration Rapid Test	Test fertilità	OSC-902	Low Risk	12.05.01.90
<b>SCREEN H. PYLORI ANTIBODY</b> H.pylori Antibody Rapid Test	Test H.Pylori Antibody	IHP-402	Low Risk	15.01.04.03
<b>SCREEN H. PYLORI ANTIGEN</b> H.pylori Antigen Rapid Test	Test H.Pylori Antigen	IHP-602	Low Risk	15.01.04.01
<b>SCREEN MONO TEST</b> Mono Rapid Test	Test Mononucleosi	IMO-402	Low Risk	15.70.90.03
<b>SCREEN ROTAVIRUS</b> Rotavirus Rapid Test	Test Rotavirus	IRO-602	Low Risk	15.04.80.06
<b>SCREEN ADENOVIRUS TEST</b> Adenovirus Rapid Test Cassette	Test Adenovirus	IAD-602	Low Risk	15.04.80.01
<b>SCREEN CMV IGM</b> CMV IgM Rapid test Cassette	Test CMV Igm	ICM-302	Low Risk	15.04.02.06
<b>SCREEN GONORRHEA</b> Gonorrhea Rapid Test Cassette	Test Gonorrhea	IGO-502	Low Risk	15.01.02.01
<b>SCREEN HSV 1/2 IGM</b> HSV 1/2 IgM Rapid Test Cassette	Test HSV1/2 Igm	ISM-302	Low Risk	15.04.03.06
<b>SCREEN NICOTINA-S</b> COT Oral Fluid Test	Test Cotinina	DCT-802	Low Risk	12.09.01.08
<b>SCREEN NICOTINA</b> COT Rapid Test Cassette	Test Cotinina	DCT-114	Low Risk	12.09.01.08
<b>SCREEN 5</b> One Step Drug Test Card	COC300-AMP1000-MET1000-OPI2000- THC50	DOA-154-C	Low Risk	12.09.01.90
<b>SCREEN GENERIC TEST URINA 12</b> Urinalysis Reagent Strips	Test Urina	URS- 12MA:11MA	Low Risk	11.70.02.90

<b>SCREEN READER</b> Rapid Test Reader	Strumento di Stampa	SCREEN0016	Low Risk	29.01.10.01
<b>SCREEN MALARIA – P.F./P.V.</b> Malaria P.F. /P.V. Rapid Test	Test Malaria P.F./P.V.	IMPV-402	Low Risk	15.05.10.09
<b>SCREEN TEST SIFILIDE</b> Syphilis Rapid Test	Test Syphilis	ISY-402	Low Risk	15.01.03.03
<b>SCREEN TEST TUBERCULOSI</b> Tuberculosis Rapid Test	Test Tuberculosis (Isotipi IgG, IgM e IgA)	ITB-402	Low Risk	13.05.02.02
<b>SCREEN 12</b> 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
<b>SCREEN 10</b> Multi Drug Rapid Test Panel	MOP/COC/THC/AMP500/MET500/ MTD/BAR/BZD/TCA/BUP	DOA-1104	Low Risk	12.09.01.90
<b>SCREEN 9</b> Multi Line Drug Rapid Test Cassette	AMP500/COC+BAR/MOR+MDMA500/MTD +TCA/BZO+THC	DOA-195-S	Low Risk	12.09.01.90
<b>SCREEN CRP TEST</b> C-Reactive Protein Rapid Test	C-reactive protein rapid test	CCR-402	Low Risk	12.70.13.90
<b>SCREEN 1</b> One step drug test card	Amphetamine	DAM-114	Low Risk	12.09.01.01
<b>SCREEN 1</b> One step drug test card	Barbiturates	DBA-114	Low Risk	12.09.01.03
<b>SCREEN 1</b> One step drug test card	Benzodiazepine	DBZ-114	Low Risk	12.09.01.04
<b>SCREEN 1</b> One step drug test card	Cocaine	DCO-114	Low Risk	12.09.01.06
<b>SCREEN 1</b> One step drug test card	Ketamine	DKE-114	Low Risk	12.09.01.90
<b>SCREEN 1</b> One step drug test card	Methamphetamine	DMA-114	Low Risk	12.09.01.02
<b>SCREEN 1</b> One step drug test card	Ecstasy	DMD-114	Low Risk	12.09.01.02
<b>SCREEN 1</b> One step drug test card	Opiates	DOP-114	Low Risk	12.09.01.13

<b>SCREEN 1</b> One step drug test card	Marijuana	DTH-114	Low Risk	12.09.01.05
<b>SCREEN 1</b> One step drug test card	Buprenorphine	DBU-114	Low Risk	12.09.01.90
<b>SCREEN 1</b> One step drug test card	Methadone	DMT-114	Low Risk	12.09.01.10
<b>SCREEN 8</b> Multi Drug Rapid Test Panel	COC/AMP/THC/MTD MOP/BAR/BZO/TCA	DOA-184	Low Risk	12.09.01.90
<b>SCREEN 10</b> Multi Drug Rapid Test Panel	COC/AMP/MET/THC MTD/OPI/PCP/BAR BZO/TCA	DOA-1104(P)	Low Risk	12.09.01.90
<b>SCREEN FOB TEST</b> FOB Rapid Test	Fecal Occult Blood	TFO-602	Low Risk	11.70.03.01
<b>SCREEN MIOGLOB./TROPON./CK-MB</b> Myoglobin/Troponin i/CK-MB Combo Test	Other Cardiac Marker Rapid Tests	CMA-435	Low Risk	12.70.13.90
<b>SCREEN GENERIC TEST URINA 11</b> Urinalysis Reagent Strips	Test Urina	U031-11	Low Risk	11.70.02.02
<b>SCREEN 8 +AD</b> Multi Drug Rapid Test Panel	AMP500/BUP/COC/MDMA500 MET500/MOR/MTD/THC pH AND CREATININE	SDUA-184	Low Risk	12.09.01.90
<b>SCREEN CUP 8+AD</b> Multi Drug Rapid Test Cup	COC/AMP500ng/MET500ng/THC MOP/MDMA/MTD/BUP pH AND CREATININE	SDOA-184	Low Risk	12.09.01.90
<b>SCREEN 7+AD</b> Multi Drug Rapid Test Panel	AMP500/COC/MDMA500/MET500 MOR/MTD/THC pH AND CREATININE	SDUA-174	Low Risk	12.09.01.90
<b>SCREEN 6-S2</b> Multi Drug Rapid Test Oral Fluid	OPI/COC/THC/OXY/AMP/MAMP-MDMA	DSD-865-A	Low Risk	12.09.01.90
<b>SCREEN CUBE 7-S</b> 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
<b>SCREEN MIDSTREAM 6-S</b> 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
<b>SCREEN MIDSTREAM 6-S4</b> Multi Drug Rapid Test Oral Fluid	OPI/COC/THC/AMP/ MET-MDMA/MTD	DSD-863-D	Low Risk	12.09.01.90
<b>SCREEN MIDSTREAM 6-S3</b> Multi Drug Rapid Test Oral Fluid	OPI/COC/THC/AMP/ MET-MDMA/BZO	DSD-863-C	Low Risk	12.09.01.90

<b>SCREEN MIDSTREAM 6-S2</b> Multi Drug Rapid Test Oral Fluid	OPI/COC/THC/AMP/ MET-MDMA/SMA-K2	DSD-863-B	Low Risk	12.09.01.90
<b>SCREEN GENERIC TEST URINA 10</b> Urinalysis Reagent Strips	Test Urina	U031-10	Low Risk	11.70.02.02
<b>SCREEN MIDSTREAM 6-S-MED</b> 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
<b>SCREEN TEST ADULTERAZIONE</b> Adulteration Strips	Creatinina, Nitriti, Glutaraldeide, pH, Peso Specifico e Ossidanti/Clorocromato di piridinio (PCC)	SCR0011	Low Risk	11.70.02.02
<b>SCREEN CUP 10 + A + AD</b> 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
<b>SCREEN CUP 10 + A + AD</b> 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
<b>SCREEN CUP 12 + A + AD</b> 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
<b>SCREEN CUP 12 + A + AD</b> 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
<b>SCREEN CUP 10-S</b> 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
<b>SCREEN ANALYSIS METER 10</b> Urine Analysis Meter	Lettore Test 10 Parametri	URM-100	Low Risk	24.06.10.01
<b>SCREEN ANALYSIS METER 11</b> Urine Analysis Meter	Lettore Test 11 Parametri	URM-110	Low Risk	24.06.10.01
<b>SCREEN ANALYSIS METER 12</b> Urine Analysis Meter	Lettore Test 12 Parametri	URM-200	Low Risk	24.06.10.01
<b>SCREEN PROCALCITONINA</b> Procalcitonin (PCT) Rapid Test	Procalcitonin (PCT) Rapid Test	CPC-402	Low Risk	12.06.90.16
<b>SCREEN CUP 8+AD</b> 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
<b>SCREEN TEST MYCOPLASMA</b> Mycoplasma Pneumoniae Antigen Test	Mycoplasma Pneumoniae Antigen Rapid Test	IMP-502	Low Risk	15.01.08.01
<b>SCREEN CUP 7+AD</b> 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
<b>SCREEN TEST CALPROTECTINA</b> Calprotectin Rapid Test Cassette	Calprotectin	OCAL-602	Low Risk	12.01.90.10

<b>SCREEN CLOSTRIDIUM TEST</b> Clostridium difficile GHD Rapid Test	Clostridium	ICD-602	Low Risk	15.01.90.02
<b>SCREEN HCG TEST</b> Pregnancy Rapid Test Cassette	Human Chorionic Gonadotropin	FHC-102	Low Risk	12.05.02.05
<b>SCREEN TEST NOROVIRUS</b> Norovirus Rapid Test	Norovirus	INO-602	Low Risk	15.04.80.16
<b>SCREEN HCG TEST</b> Pregnancy Rapid Test Cassette H/S	Human Chorionic Gonadotropin	FHC-U102	Low Risk	12.05.02.05
<b>SCREEN 10</b> 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
<b>SCREEN 5</b> Multi Line Drug Rapid Test Cassette	OXY100/EDDP300/PCP25/TML100/K2-30	DOA-155-S1	Low Risk	12.09.01.90
<b>SCREEN 5</b> Multi Line Drug Rapid Test Cassette	PPX300/KET300/FYL10/TCA1000/BUP10	DOA-155-S2	Low Risk	12.09.01.90
<b>SCREEN CLOSTRIDIUM A+B</b> clostridium Difficile Toxin A+Toxin B	Clostridium difficile Rapid Toxin A+Toxin B	ICDT-625	Low Risk	15.01.90.02
<b>SCREEN 12</b> 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
<b>SCREEN CUP 7+ADU</b> 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
<b>SCREEN CHIKUNGUNYA TEST</b> Chikungunya IGG/IGM Rapid Test	Test Chikungunya	ICHI-402	Low Risk	15.04.80.25
<b>SCREEN ZIKA TEST</b> NS1 Zika Rapid Test	Test Zika	IZIG-402	Low Risk	15.70.90.90
<b>SCREEN TEST EPATITE A – HAV</b> HAV IGM Rapid Test Cassette	Test Epatite A – Hav IgM	IHA-302	Low Risk	15.02.01.06
<b>SCREEN TEST LEGIONELLA</b> Legionella Pneumophila Rapid Test	Test Legionella	ILEG-102	Low Risk	15.01.05.01
<b>SCREEN TEST VITAMINA D</b> Vitamin D Rapid Test	Test Vitamina D	OVD-402	Low Risk	12.06.03.10
<b>SCREEN TEST PNEUMOCOCCO</b> S. Pneumoniae Antigen Test	Test Streptococcus pneumoniae	ISP-102	Low Risk	15.70.01.09
<b>SCREEN CRYPTOSPORIDIUM</b> Cryptosporidium Antigen Test	Cryptosporidium Antigen Rapid Test	ICR-602	Low Risk	14.05.02.03
<b>SCREEN DENGUE COMBO</b> Dengue Combo Rapid Test	Dengue Combo Rapid Test	IDEC-425	Low Risk	15.04.80.11

<b>SCREEN DENGUE NS1</b> Dengue NS1 Rapid Test	Dengue NS1 Rapid Test	IDES-402	Low Risk	15.04.80.11
<b>SCREEN GIARDIA LAMBLIA</b> Giardia Lamblia Rapid Test	Giardia Lamblia Rapid Test	IGL-602	Low Risk	15.05.10.08
<b>SCREEN CAMPYLOBACTER</b> Campylobacter Rapid Test Cassette	Campylobacter Test Rapido a Cassetta	ICAM-602	Low Risk	15.01.14.01
<b>SCREEN CLAMIDIA TEST</b> Clamidia Rapid Test Cassette	Clamidia Test rapido a cassetta	ICH-502	Low Risk	15.01.01.01
<b>SCREEN DRUG TEST CAPELLO</b> 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
<b>SCREEN RUBELLA IGM</b> Rubella IGM Rapid Test	Test Rapido Rosolia	IRM-302	Low Risk	15.04.01.06
<b>SCREEN PSA TEST</b> PSA Rapid Test	PSA Test rapido a cassetta	TPS-402	Low Risk	12.03.01.32
<b>SCREEN TEST COVID-19</b> 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
<b>SCREEN TEST COVID-19</b> 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
<b>SCREEN TEST COVID-19</b> 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
<b>SCREEN TEST COVID-19 AG</b> Covid-19 Antigen Rapid Test	Covid-19 Antigen Rapid Test Test Rapido a cassetta	ICOV-502	Low Risk	15.70.90.90
<b>SCREEN TEST COVID-19+FLU A/B</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
<b>SCREEN TEST COVID-19 SALIVA</b> COVID-19 ANTIGEN RAPID TEST ORAL FLUID	Test rapido Antigene COVID-19 (Fluido orale)	ICOV-802	Low Risk	15.70.90.90