# STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as non-exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This Statement letter will be valid from Feb.21th,2023 to Feb.20th, 2024.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2023/2/21

Digitally signed by Monastîrschii Viorica
Date: 2023.03.31 13:16:07 EEST
Reason: MoldSign Signature
Location: Moldova

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
Add: **3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China**
电话 Tel:+86-572-5226111　　传真 Fax: +86-572-5226222　邮编 P.C.:313300

浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD

CE-DOC-OG318
Version 1.0

# EC Declaration of Conformity

In accordance with Directive 98/79/EC

**Legal Manufacturer:** *Zhejiang Orient Gene Biotech Co., Ltd*

**Legal Manufacturer Address:** *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

| | |
|---|---|
| One Step Drugs of Abuse Test Strip (Urine) | GBXXX-101 |
| One Step Drugs of Abuse Test Cassette (Urine) | GBXXX-102 |
| One Step Drugs of Abuse Test Dip Card (Urine) | GBXXX-105 |

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

**EC Representative's Name:** CMC Medical Devices & Drugs S.L

**EC Representative's Address:** C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: April 4, 2022

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

# Certificate

## No. Q5 092305 0001 Rev. 01

**Holder of Certificate:** **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**


**Scope of Certificate:** **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 01

**Report No.:** SH2198802

**Valid from:** 2022-04-11
**Valid until:** 2024-03-16

**Date,** 2022-04-11

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

# Certificate

## No. Q5 092305 0001 Rev. 01

**Applied Standard(s):**

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

**Facility(ies):**

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

# Zhejiang Orient Gene Biotech Co., LTD

## CERTIFICATE OF ANALYSIS

**Product Name:**
**Purchase NO.:**
**Lot NO.:**
**Quantity:**
**Expiration Date:**

| ANALYSIS | CONTROLS | SPECIFICATIONS | TEST RESULT |
|---|---|---|---|
| Amphetamine （AMP:1000ng） | Drug-free Urine | Negative | Negative |
| | 500 ng/ml D-Amphetamine | Negative | Negative |
| | 1500 ng/ml D-Amphetamine | Positive | Positive |
| Barbiturates （BAR:300ng） | Drug-free Urine | Negative | Negative |
| | 150 ng/ml Secobarbital | Negative | Negative |
| | 450 ng/ml Secobarbital | Positive | Positive |
| Buprenorphine （BUP:10ng） | Drug-free Urine | Negative | Negative |
| | 5ng/ml Buprenorphine | Negative | Negative |
| | 15ng/ml Buprenorphine | Positive | Positive |
| Benzodiazepines （BZO:300ng） | Drug-free Urine | Negative | Negative |
| | 150 ng/ml Oxazepam | Negative | Negative |
| | 450 ng/ml Oxazepam | Positive | Positive |
| Cocaine （COC:300ng） | Drug-free Urine | Negative | Negative |
| | 150ng/ml Benzoylecgonine | Negative | Negative |
| | 450ng/ml Benzoylecgonine | Positive | Positive |
| Cotinine(COT:200ng) | Drug-free Urine | Negative | Negative |
| | 100ng/ml Cotinine | Negative | Negative |
| | 300ng/ml Cotinine | Positive | Positive |
| Ecstasy （MDMA500ng） | Drug-free Urine | Negative | Negative |
| | 250ng/ml D,L-Methylenedioxy-methamphetamine | Negative | Negative |
| | 750ng/ml D,L-Methylenedioxy-methamphetamine | Positive | Positive |
| Ethyl Glucuronide (ETG500ng) | Negative Control | Negative | Negative |
| | Positive Control | Positive | Positive |
| Ethyl Glucuronide (ETG300ng) | Negative Control | Negative | Negative |
| | Positive Control | Positive | Positive |
| Fentanyl (FEN:200ng) | Drug-free Urine | Negative | Negative |
| | 100ng/ml Fentanyl | Negative | Negative |
| | 300ng/ml Fentanyl | Positive | Positive |
| Gabapentin （GAB 1000ng） | Drug-free Urine | Negative | Negative |
| | 500ng/ml Gabapentin | Negative | Negative |
| | 1500ng/ml Gabapentin | Positive | Positive |

| | | | |
|---|---|---|---|
| K2（50ng） | Drug-free Urine | Negative | Negative |
| | 25ng/ml JWH-073/JWH-018 | Negative | Negative |
| | 100ng/ml JWH-073/JWH-018 | Positive | Positive |
| Ketamine (KET:2000ng) | Drug-free Urine | Negative | Negative |
| | 1000ng/ml Ketamine | Negative | Negative |
| | 3000 ng/ml Ketamine | Positive | Positive |
| Marijuana (THC:50ng) | Drug-free Urine | Negative | Negative |
| | 25 ng/ml 11-nor-Δ9-THC-9-COOH | Negative | Negative |
| | 75 ng/ml 11-nor-Δ9-THC-9-COOH | Positive | Positive |
| Methadone Metabolite (EDDP300ng) | Drug-free Urine | Negative | Negative |
| | 150ng/ml 2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine | Negative | Negative |
| | 450ng/ml 2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine | Positive | Positive |
| Methylphenidate （MPD300ng） | Drug-free Urine | Negative | Negative |
| | 150ng/ml Methylphenidate | Negative | Negative |
| | 450ng/ml Methylphenidate | Positive | Positive |
| Methamphetamine （MET:1000ng） | Drug-free Urine | Negative | Negative |
| | 500 ng/ml D-Methamphetamine | Negative | Negative |
| | 1500ng/ml D-Methamphetamine | Positive | Positive |
| Morphine （MOP:300ng） | Drug-free Urine | Negative | Negative |
| | 150 ng/ml Morphine | Negative | Negative |
| | 450 ng/ml Morphine | Positive | Positive |
| Methaqualone (MQL300ng) | Drug-free Urine | Negative | Negative |
| | 150 ng/ml Methaqualone | Negative | Negative |
| | 450 ng/ml Methaqualone | Positive | Positive |
| Methadone （MTD:300ng） | Drug-free Urine | Negative | Negative |
| | 150ng/ml Methadone | Negative | Negative |
| | 450ng/ml Methadone | Positive | Positive |
| Opiate（OPI:2000ng） | Drug-free Urine | Negative | Negative |
| | 1000ng/ml Morphine | Negative | Negative |
| | 3000 ng/ml Morphine | Positive | Positive |
| Oxycodone （OXY:100ng） | Drug-free Urine | Negative | Negative |
| | 50ng/ml Oxycodone | Negative | Negative |
| | 150ng/m Oxycodone | Positive | Positive |
| Phencyclidine （PCP:25ng） | Drug-free Urine | Negative | Negative |
| | 12.5ng/ml Phencyclidine | Negative | Negative |
| | 37.5ng/ml Phencyclidine | Positive | Positive |
| Propoxyphene (PPX:300ng) | Drug-free Urine | Negative | Negative |
| | 150ng/ml Propoxyphene | Negative | Negative |
| | 450ng/ml Propoxyphene | Positive | Positive |
| Tricyclic | Drug-free Urine | Negative | Negative |

| | | | |
|---|---|---|---|
| | 500ng/ml Nortriptyline | Negative | Negative |
| | 1500ng/ml Nortriptyline | Positive | Positive |
| THC(200ng) | Drug-free Urine | Negative | Negative |
| | 100 ng/ml 11-nor-Δ9-THC-9-COOH | Negative | Negative |
| | 300 ng/ml 11-nor-Δ9-THC-9-COOH | Positive | Positive |
| Tramadol (TRA:200ng) | Drug-free Urine | Negative | Negative |
| | 100ng/ml Tramadol | Negative | Negative |
| | 300ng/ml Tramadol | Positive | Positive |
| Norfentanyl （FEN10ng） | Drug-free Urine | Negative | Negative |
| | 5ng/ml Norfentanyl | Negative | Negative |
| | 15ng/ml Norfentanyl | Positive | Positive |
| Norfentanyl （20ng） | Drug-free Urine | Negative | Negative |
| | 10ng/ml Norfentanyl | Negative | Negative |
| | 30ng/ml Norfentanyl | Positive | Positive |
| Norfentanyl （200ng） | Drug-free Urine | Negative | Negative |
| | 100ng/ml Norfentanyl | Negative | Negative |
| | 300ng/ml Norfentanyl | Positive | Positive |
| Lysergic acid diethylamide （LSD 20ng） | Drug-free Urine | Negative | Negative |
| | 10 ng/ml Lysergic acid diethylamide | Negative | Negative |
| | 30 ng/ml Lysergic acid diethylamide | Positive | Positive |
| 6-Monoacetylmorphine | Drug-free Urine | Negative | Negative |
| | 5ng/ml 6-Monoacetylmorphine | Negative | Negative |
| | 15ng/ml 6-Monoacetylmorphine | Positive | Positive |
| Hydromorphone （HMO 300ng） | Drug-free Urine | Negative | Negative |
| | 150ng Hydromorphone | Negative | Negative |
| | 450ng Hydromorphone | Positive | Positive |
| Hydrocodone （HCD 10ng） | Drug-free Urine | Negative | Negative |
| | 5ng Hydrocodone | Negative | Negative |
| | 15ng Hydrocodone | Positive | Positive |
| K2/K3 (K2 50ng/K3 10ng) | Drug-free Urine | Negative | Negative |
| | 25ng K2 | Negative | Negative |
| | 75ng K2 | Positive | Positive |
| | 5ng K3 | Negative | Negative |
| | 15ng K3 | Positive | Positive |
| Pinaca （K3 10ng） | Drug-free Urine | Negative | Negative |
| | 5ng Pinaca | Negative | Negative |
| | 15ng Pinaca | Positive | Positive |
| Kratom | Drug-free Urine | Negative | Negative |
| | 125ng/ml Kratom (Mitragynine) | Negative | Negative |
| | 375ng/ml Kratom(Mitragynine) | Positive | Positive |

# Zhejiang Orient Gene Biotech Co., LTD

| | | | |
|---|---|---|---|
| Soma<br>(Soma 1000ng/ml) | Drug-free Urine | Negative | Negative |
| | 500ng/ml Soma(Carisoprodol) | Negative | Negative |
| | 1500ng/ml Soma(Carisoprodol) | Positive | Positive |

Conclusion: ☼Pass:All results meet QC standard.

□Fail

**Product Manufacturing**

The product specified above has been manufactured in accordance with relevant regulations controlling the diagnostic and medical device industry for the United States of America. No radioactive or latex materials of any kind are utilized in the product, or in the manufacture of the product.
The product specified above does not contain any virus, reagent by-product of the same, or metabolic by-product of Hepatitis A, B, C, or D, or the antibodies for the human autoimmune immunodeficiency (AIDS).

Test by :

QC Supervisor:

Date:

# One Step Multi-Drug Screen Test Dip Card (Urine) Package Insert

CE

Package insert for testing of any combination of the following drugs: Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cotinine, Ecstasy, Ethyl Glucuronide, Fentanyl, Lysergic acid diethylamide, Marijuana, Methadone, EDDP (Methadone Metabolites), Ketamine, Methamphetamine, Methaqualone, Methylenedioxypyrovalerone, 6-Monoacetylmorphine, Morphine, Oxycodone, Phencyclidine, Propoxyphene, K2 (Synthetic Cannabinoid), Tramadol and Tricyclic Antidepressants.

*A rapid, one step screening test for the simultaneous, qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cotinine, Ecstasy, Ethyl Glucuronide, Fentanyl, Lysergic acid diethylamide, Marijuana, Methadone, EDDP (Methadone Metabolites), Ketamine, Methamphetamine, Methaqualone, Methylenedioxypyrovalerone, 6-Monoacetylmorphine, Morphine, Oxycodone, Phencyclidine, Propoxyphene, K2 (Synthetic Cannabinoid), Tramadol and Tricyclic Antidepressants and the metabolites in human urine.*

*For healthcare professional in vitro diagnostic use only.*

## INTENDED USE

Urine based Drug tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.

The **One Step Multi-Drug Screen Test Dip Card (Urine)** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs, drug metabolites and alcohol at the following cut-off concentrations in urine:[1]

| Test | Calibrator | Cut-off (ng/mL) |
|---|---|---|
| Amphetamine (AMP) | D-Amphetamine | 1,000 |
| Amphetamine (AMP) | D-Amphetamine | 500 |
| Amphetamine (AMP) | D-Amphetamine | 300 |
| Barbiturates (BAR) | Secobarbital | 300 |
| Barbiturates (BAR) | Secobarbital | 200 |
| Benzodiazepines (BZO) | Oxazepam | 300 |
| Benzodiazepines (BZO) | Oxazepam | 200 |
| Buprenorphine (BUP) | Buprenorphine | 10 |
| Cocaine (COC ) | Benzoylecgonine | 300 |
| Cocaine (COC ) | Benzoylecgonine | 150 |
| Cotinine (COT) | Cotinine | 200 |
| MDMA (Ecstasy) | D,L-3,4-Methylenedioxymethamphetamine (MDMA) | 500 |
| Ethyl Glucuronide (ETG) | Ethyl Glucuronide | 500 |
| Ethyl Glucuronide (ETG) | Ethyl Glucuronide | 300 |
| Fentanyl (FEN) | Fentanyl | 300 |
| Fentanyl (FEN) | Fentanyl | 200 |
| Fentanyl (FEN) | Fentanyl | 100 |
| Fentanyl (FEN) | Norfentanyl | 20 |
| Ketamine (KET) | Ketamine | 1,000 |
| Ketamine (KET) | Ketamine | 100 |
| Lysergic acid diethylamide (LSD) | D-lysergic acid diethylamide | 20 |
| Marijuana (THC ) | 11-nor-$\Delta^9$-THC-9 COOH | 50 |
| Marijuana (THC ) | 11-nor-$\Delta^9$-THC-9 COOH | 25 |
| Marijuana (THC ) | 11-nor-$\Delta^9$-THC-9 COOH | 20 |
| Methadone (MTD) | Methadone | 300 |
| EDDP (Methadone Metabolites) | 2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP) | 300 |
| EDDP (Methadone Metabolites) | 2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP) | 100 |
| Methamphetamine (MET, mAMP ) | D-Methamphetamine | 1,000 |
| Methamphetamine (MET, mAMP ) | D-Methamphetamine | 500 |
| Methamphetamine (MET, mAMP ) | D-Methamphetamine | 300 |
| Methaqualone (MQL) | Methaqualone | 300 |
| Methylenedioxypyrovalerone | 3,4-Methylenedioxypyrovalerone | 1,000 |
| (MDPV) | | |
| 6-Monoacetylmorphine (6-MAM) | 6-Monoacetylmorphine | 10 |
| Morphine (MOP 300) | Morphine | 300 |
| Morphine (OPI, MOP 2000 ) | Morphine | 2,000 |
| Oxycodone (OXY ) | Oxycodone | 100 |
| Phencyclidine (PCP) | Phencyclidine | 25 |
| Propoxyphene (PPX) | Propoxyphene | 300 |
| K2 Synthetic Cannabinoid | JWH-073/JWH-018 | 50 |
| K2 Synthetic Cannabinoid | JWH-073/JWH-018 | 25 |
| Tramadol (TRA) | Tramadol | 200 |
| Tricyclic Antidepressants (TCA) | Nortriptyline | 1,000 |
| Alcohol (ALC) | Ethanol | >0.04% B.A.C |

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

**This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.**

## SUMMARY

### AMPHETAMINE (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

### BARBITURATES (BAR)

Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death. Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine.

The approximate detection time limits for Barbiturates are:

Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days

Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days.

### BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception. Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in the urine is 3-7 days.

### BUPRENORPHINE (BUP)

Buprenorphine is a semisynthetic opioid analgesic derived from thebain, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists because of the "ceiling effect", which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses. However, it has also been shown that Buprenorphine has abuse potential and may itself cause dependency. Subutex® and a Buprenorphine/Naloxone combination product, Suboxone® are the only two forms of Buprenorphine that have been approved by FDA in 2002 for use in opioid addiction treatment. Buprenorphine was rescheduled from Schedule V to Schedule III drug just before FDA approval of Suboxone and Subutex.

### COCAINE (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylecgonine.[1,2] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[2]

### COTININE (COT)

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%.[1] While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration.[2] Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

### MDMA (ECSTASY)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

### ETHYL GLUCURONIDE (ETG)

Ethyl Glucuronide (EtG) is a direct metabolite of ethanol alcohol. The presence of EtG in the urine can be used to detect recent alcohol consumption, even after the ethanol alcohol is no longer measurable. Consequently, the presence of EtG in the urine is a definitive indicator that alcohol has been ingested. Traditional laboratory practices typically measure the amount of alcohol present in the body. Depending on the amount of alcohol that has been consumed, this method usually reveals alcohol ingestion within the past few hours.

The presence of EtG in the urine, on the other hand, demonstrates that ethanol alcohol was ingested within the past three or four days, or roughly 80 hours after the ethanol alcohol has been metabolized by the body. As a result, it can be determined that a urine alcohol test employing EtG is a more accurate indicator of the recent consumption of alcohol as opposed to simply measuring for the existence of ethanol alcohol.

### FENTANYL (FEN)

Fentanyl is a synthetic opioid. It has the brand names of Sublimaze, Actiq, Durogestic, Fentora and others. The Fentanyl drug is approximately 100 times more potent than morphine, with 100 micrograms of fentanyl approximately equivalent to 10 mg. of morphine or 75 mg. of meperidine in analgesic activity. The Fentanyl drug is a potent narcotic analgesic with rapid onset and short duration of action. Historically, the fentanyl drug has been used to treat chronic breakthrough pain and is commonly used pre-procedures. Illicit use of pharmaceutical fentanyl drugs first appeared in the mid-1970s. Because the effects of the fentanyl drug last for only a very short time, it is even more addictive than heroin. Regular users may become addicted very quickly. The Fentanyl drug is much more potent than heroin, and tends to produce significantly worse respiratory depression, making it somewhat more dangerous than heroin to users. Overdose of the fentanyl drug has caused death. In the United States, the fentanyl drug is classified as a Schedule II controlled substance.

### KETAMINE (KET)

Ketamine is a short-acting "dissociative" anesthetic due to its ability to separate perception from sensation. It also has hallucinogenic and painkilling qualities that seem to affect people in very different ways. Ketamine is chemically related to PCP ('Angel Dust'). Ketamine is occasionally administered to people but, more commonly, is used by vets for pet surgery. Generally street K is

most often diverted in liquid form from vets' offices or medical suppliers. Ketamine generally takes 1-5 minutes to take effect. Snorted ketamine takes a little longer at 5-15 minutes. Depending on how much and how recently one has eaten, oral ketamine can take between 5 and 30 minutes to take effect. The primary effects of ketamine last approximately a 30-45 minutes if injected, 45-60 minutes when snorted, and 1-2 hours if used orally. The Drug Enforcement Administration reports that the drug can still affect the body for up to 24 hours.

**LYSERGIC ACID DIETHYLAMIDE (LSD)**

D-lysergic acid diethylamide (LSD) is the most potent hallucinogenic substance known to man. Dosages of LSD are measured in micrograms, or millionths of a gram. By comparison, dosages of cocaine and heroin are measured in milligrams, or thousandths of a gram. Compared to other hallucinogenic substances, LSD is 100 times more potent than psilocybin and psilocin and 4,000 times more potent than mescaline. The dosage level that will produce a hallucinogenic effect in humans generally is considered to be 25 micrograms. Over the past several years, the potency of LSD obtained during drug law enforcement operations has ranged between 20 and 80 micrograms per dosage unit. The Drug Enforcement Administration (DEA) recognizes 50 micrograms as the standard dosage unit equivalency.

**MARIJUANA (THC)**

THC ($\Delta^9$-tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When smoked or orally administered, it produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long term relatively heavy use may be associated with behavioral disorders. The peak effect of smoking marijuana occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-$\Delta^9$-tetrahydrocannabinol-9-carboxylic acid ($\Delta^9$-THC-COOH).

**METHADONE (MTD)**

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of Morphine dependence (heroin, Vicodin, Percocet, Morphine). The pharmacology of Oral Methadone is very different from IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone. Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from Methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.

**EDDP**

EDDP is the primary metabolite of methadone. Methadone is a controlled substance and is used for detoxification and maintenance of opiate-dependent patients. Patients on methadone maintenance may exhibit methadone (parent) levels that account for 5-50% of the dosage and 3-25% of EDDP in urinary excretion during the first 24 hours. The tampering of specimens by spiking the urine with methadone can be prevented. Also, renal clearance of EDDP is not affected by urinary pH; therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone test. Methadone is an unusual drug in a sense that its primary urinary metabolites (EDDP and EMDP) are cyclic in structure. Thus, they are very difficult to detect with immunoassays targeted to the native compound. Exacerbating this problem, there is a subsection of the population classified as "extensive metabolizers" of methadone. In these individuals, a urine specimen may not contain enough parent methadone to yield a positive drug screen even if the individual is in compliance with their methadone maintenance.

**METHAMPHETAMINE (MET, mAMP)**

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulaDtion of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion. The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and delaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use.

**METHAQUALONE (MQL)**

Methaqualone (Quaalude, Sopor) is a quinazoline derivative that was first synthesized in 1951 and found clinically effective as a sedative and hypnotic in 1956. It soon gained popularity as a drug of abuse and in 1984 was removed from the US market due to extensive misuse. It is occasionally encountered in illicit form, and is also available in Europeon countries in combination with diphenhydramine (Mandrax). Methaqualone is extensively metabolized in vivo principally by hydroxylation at every possible position on the molecule. At least 12 metabolites have been identified in the urine.

**METHYLENEDIOXYPYROVALERONE (MDPV)**

Bath salts', a form of designer drugs, also promoted as 'plant food' or 'research chemicals', is sold mainly in head shops, on the Internet, and at other retail locations. Designer drugs were developed in recent years to subvert law enforcement and drug testing agencies and are advertised a'legal'highs. The technical term for 'bath salts' is substituted cathinone. Substituted cathinone is synthetic, concentrated version of the stimulant chemical in Khat. Khat is a plant that is cultivated and used in East Africa and the Middle East. It has a stimulant effect on the user and can be quite dangerous. The white crystals resemble legal bathing salts, thus the name of 'bath salts'. In 2009 and 2010 there was a significant rise in the abuse of synthetic cathinone, initially in the United Kingdom and the rest of Europe, and subsequently in the US and Canada,

Established as one of the main ingredients for 'bath salts', among other synthetic stimulants like Mephedrone, Methylone, Butylone and Methedrone, MDPV started appearing around 2004 when it was popularized as a club drug, often used in combination with alcohol, GHB, cannabis and other abused drugs, for its desired effects such as euphoria, alertness, talkativeness, and sexual arousal. There are currently no prescribed used for the synthetic stimulants.

While synthetic stimulants appear to affect users in ways similar to amphetamines, ecstasy and cocaine, reports concerning aggression, tachycardia, paranoia and suicide suggest that they may be more acutely toxic. These negative effects have resulted in an increase of ER visits and hospitalizations, severe psychotic and violent episodes, self-inflicted wounds, suicide and an alarming increase in abuse-related deaths. U.S. Poison Control and National Drug Intelligence have all issued health warnings, noting nationwide emergency room visits related to these drugs. In October 2011, the DEA announced an emergency ban on MDPV, Methylone and Mephedrone, making testing for these substances more vital than ever.

**6-MONOACETYLMORPHINE (6-MAM)**

6-Monoacetylmorphine (6-MAM) is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-acetylmorphine (3-ACM). 6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excreted in the urine. Since 6-ACM is a unique metabolite to heroin, its presence in the urine confirms that heroin was the opioid used. This is significant because on a urine immunoassay drug screen, the test typically tests for morphine, which is a metabolite of a number of legal and illegal opiates/opioids such as codeine, morphine sulphate, and heroin. 6-MAM remains in the urine for no more than 24 hours so a urine specimen must be collected soon after the last heroin use, but the presence of 6-MAM guarantees that heroin was in fact used as recently as within the last day.

**MORPHINE (MOP)**

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor. Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.[4]

**OXYCODONE (OXY)**

Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one, dihydrohydroxycodeinone] is a semi-synthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone is a Schedule II narcotic analgesic and is widely used in clinical medicine. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, euphoria, feelings of relaxation, respiratory depression, constipation, papillary constriction, and cough suppression. Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical trade names as OxyContin® (controlled release), OxyIR®, OxyFast® (immediate release formulations), or Percodan® (aspirin) and Percocet® (acetaminophen) that are in combination with other nonnarcotic analgesics. Oxycodone's behavioral effects can last up to 5 hours. The controlled-release product, OxyContin®, has a longer duration of action (8-12 hours).

**PHENCYCLIDINE (PCP)**

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations. Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine. PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[5] Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

**PROPOXYPHENE (PPX)**

Propoxyphene (PPX) is a mild narcotic analgesic found in various pharmaceutical preparations, usually as the hydrochloride or napsylate salt. These preparations typically also contain large amounts of acetaminophen, aspirin, or caffeine. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels. In human, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

**SYNTHETIC MARIJUANA (K2)**

Synthetic Marijuana or K2 is a psychoactive herbal and chemical product that, when consumed, mimics the effects of Marijuana. It is best known by the brand names K2 and Spice, both of which have largely become genericized trademarks used to refer to any synthetic Marijuana product. The studies suggest that synthetic marijuana intoxication is associated with acute psychosis, worsening of previously stable psychotic disorders, and also may have the ability to trigger a chronic (long-term) psychotic disorder among vulnerable individuals such as those with a family history of mental illness.

Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 72 hours after smoking (depending on usage/dosage).

As of March 1, 2011, five cannabinoids, JWH-018, JWH-073, CP-47, JWH-200 and cannabicyclo hexanol are now illegal in the US because these substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety. JWH-018 was developed and evaluated in basic scientific research to study structure activity relationships related to the cannabinoid receptors. JWH-073 has been identified in numerous herbal products, such as "Spice", "K2", K3" and others. These products may be smoked for their psychoactive effects.

**TRAMADOL (TRA)**

Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors. It has been prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome.[2] Large doses of Tramadol could develop tolerances and physiological dependency and lead to its abuse. Both Δ (d) and L forms of the isomers are controlled substances. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O- demethylation, glucoronidation or sulfation in the liver.

**TRICYCLIC ANTIDEPRESSANTS (TCA)**

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

**ALCOHOL (ALC)**

Excess or inappropriate consumption of alcohol is a common and pervasive social problem. It is a contributory factor to many accidents, injuries and medical conditions. Screening of individuals for alcohol consumption is an important method for the identification of individuals who might be at risk due to alcohol use or intoxication. Screening is also an important deterrent against inappropriate alcohol consumption. The blood alcohol concentration at which a person becomes impaired is variable dependent on the individual. Parameters specific to the individual such as physical size, weight, activity level, eating habits and alcohol tolerance all affect the level of impairment. Determination of ethyl alcohol in urine, blood and saliva is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids. Alcohol Test is designed to detect ethyl alcohol in urine specimens.

**ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) SUMMARY**

The Adulterant Test Strip contains chemically treated reagent pads. Observation of the color change on the strip compared to the color chart provides a semi-quantitative screen for Oxidants, Specific Gravity, pH, Creatinine, Nitrite and Glutaraldehyde in human urine which can help to assess the integrity of the urine specimen.

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants in the urine specimen can cause false negative results by either interfering with the test and/or destroying the drugs present in the urine. Dilution may also be used to produce false negative drug test results. To determine certain urinary characteristics such as specific gravity and pH, and to detect the presence of oxidants, Nitrite, Glutaraldehyde and Creatinine in urine are considered to be the best ways to test for adulteration or dilution.

- **Oxidants (OX)**: Tests for the presence of oxidizing agents such as bleach and peroxide in the urine.
- **Specific Gravity (S.G.)**: Tests for sample dilution. Normal levels for specific gravity will range from 1.003 to 1.030. Specific gravity levels of less than 1.003 or higher than 1.030 may be an indication of adulteration or specimen dilution.
- **pH:** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in

the range of 4.0 to 9.0. Values below pH 4.0 or above pH 9.0 may indicate the sample has been altered.

- **Nitrite (NIT)**: Tests for commercial adulterants such as Klear and Whizzies. Normal urine specimens should contain no trace of nitrite. Positive results for nitrite usually indicate the presence of an adulterant.
- **Glutaraldehyde (GLU):** Tests for the presence of an aldehyde. Glutaraldehyde is not normally found in a urine specimen. Detection of glutaraldehyde in a specimen is generally an indicator of adulteration.
- **Creatinine (CRE):** Creatinine is one way to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine may indicate dilute urine.

## PRINCIPLE

(1) The **One Step Multi-Drug Screen Test Dip Card (Urine)** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

(2) Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue on contact with alcohol in urine. The alcohol pad employs a solid phase chemistry which uses the following highly specific enzymatic reaction:

$$CH_3CH_2OH + O_2 \xrightarrow{\text{Alcohol Oxidase}} CH_3CHO + H_2O_2$$

$$H_2O_2 + DH_2 \xrightarrow{\text{Peroxidase}} D + 2H_2O$$

Blue

## REAGENTS

Each test line in the test panel contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

## ADULTERANT TESTS (SPECIMEN VALIDITY TEST) REAGENTS

| Adulteration Pad | Reactive Indicator | Buffers and Non-reactive Ingredients |
|---|---|---|
| Oxidants (OX) | 0.30% | 99.70% |
| Specific Gravity (S.G.) | 0.21% | 99.79% |
| pH | 0.06% | 99.94% |
| Nitrite (NIT) | 0.06% | 99.94% |
| Glutaraldehyde (GLU) | 0.02% | 99.98% |
| Creatinine (CRE) | 0.03% | 99.97% |

## PRECAUTIONS

- For healthcare professional *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The test dip card should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test dip card should be discarded according to local regulations.

## STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test dip card is stable through the expiration date printed on the sealed pouch. The test dip card must remain in the sealed pouch until use. Keep away from direct sunlight, moisture and heat. **DO NOT FREEZE.** Do not use beyond the expiration date.

## SPECIMEN COLLECTION AND PREPARATION

### Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

### Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

## MATERIALS

### Materials Provided

1. 25 Sealed pouches each containing a test dip card and a desiccant
2. 1 Package insert
3. 2 Color Chart Cards for Adulterant Interpretation (when applicable)
4. 2 Color Chart Cards for Alcohol (when applicable)

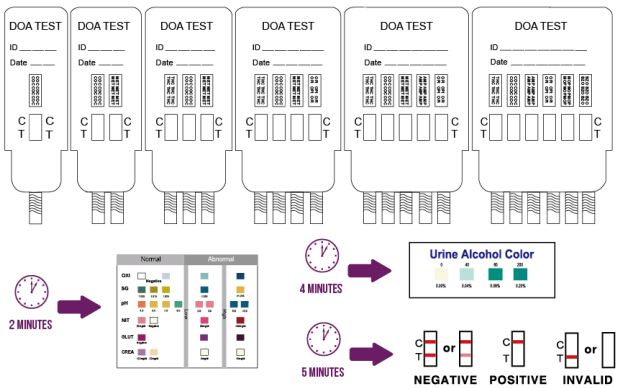
### Materials Required But Not Provided

- Timer

## DIRECTIONS FOR USE

**Allow the test dip card, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.**

1) Remove the test dip card from the foil pouch.
2) Remove the cap from the test dip card. Label the dip card with patient or control identifications.
3) Immerse the absorbent tip into the urine sample for 10-15 seconds. Urine sample should not touch the plastic dip card.
4) Replace the cap over the absorbent tip and lay the dip card flatly on a non-absorptive clean surface.
5) Read the adulteration strip at 2 minutes by comparing the colors on the adulteration strip to the enclosed color chart. If the result indicates adulteration, do not interpret the drug test results. Either retest the urine or collect another specimen.
6) Read the alcohol strip in 4 minutes by comparing the colors on the alcohol strip to the enclosed color chart.
7) Read the drug strip results at 5 minutes. **DO NOT INTERPRET RESULT AFTER 5 MINUTES.**




## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE:*** Two lines appear. One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

*NOTE: The shade of red in the test line region (Drug/T) will vary, but it should be considered negative whenever there is even a faint pink line.

**POSITIVE:** One red line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

**INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your manufacturer.

**Note**: There is no meaning attributed to line color intensity or width.

A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

**IMPORTANT**: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

***What Is A False Positive Test?***

The definition of a false positive test would be an instance where a substance is identified incorrectly by One Step Multi-Drug Screen Test Dip Card (Urine). The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

***What Is A False Negative Test?***

The definition of a false negative test is that the initial substance is present but isn't detected by One Step Multi-Drug Screen Test Dip Card (Urine). If the sample is diluted, or the sample is adulterated that may cause false negative result.

## ALCOHOL/ADULTERANT INTERPRETATION

(Please refer to the color chart)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart. No instrumentation is required.

## QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

## LIMITATIONS

1. The One Step Multi-Drug Screen Test Dip Card (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

## PERFORMANCE CHARACTERISTICS

### Accuracy

80 clinical urine specimens were analyzed by GC-MS and by the **One Step Multi-Drug Screen Test Dip Card (Urine)**. Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

| Specimen | AMP | AMP 500 | AMP 300 | BAR | BAR 200 | BUP | BZO |
|---|---|---|---|---|---|---|---|
| Positive | 91.7% | 95.8% | 96.7% | 95.0% | 94.2% | 93.3% | 91.7% |
| Negative | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Total | 95.8% | 97.9% | 98.3% | 97.5% | 97.1% | 96.7% | 95.8% |

| Specimen | BZO 200 | COC | COC 150 | COT | EDDP | EDDP 100 | ETG |
|---|---|---|---|---|---|---|---|
| Positive | 92.5% | 95.8% | 95.0% | 92.5% | 94.2% | 93.3% | 95.0% |
| Negative | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Total | 96.3% | 97.9% | 97.5% | 96.3% | 97.1% | 96.7% | 97.5% |

| Specimen | ETG 300 | FEN | FEN 200 | FEN 100 | FEN 20 | K2 | K2 25 |
|---|---|---|---|---|---|---|---|
| Positive | 95.8% | 97.5% | 95.8% | 93.3% | 97.5% | 93.3% | 95.8% |
| Negative | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Total | 97.9% | 98.8% | 97.9% | 96.7% | 98.8% | 96.7% | 97.9% |

| Specimen | KET | KET 100 | LSD | MET | MET 500 | MET 300 | MDMA |
|---|---|---|---|---|---|---|---|
| Positive | 95.8% | 91.7% | 91.7% | 95% | 95.8% | 95.8% | 95.0% |
| Negative | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Total | 97.9% | 95.8% | 95.8% | 97.5% | 97.9% | 97.9% | 97.5% |

| Specimen | MOP | MQL | 6-MAM | MTD | OPI | OXY | PCP |
|---|---|---|---|---|---|---|---|
| Positive | 96.7% | 91.7% | 92.5% | 95.0% | 88.3% | 93.3% | 91.7% |
| Negative | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Total | 98.3% | 95.8% | 96.3% | 97.5% | 94.2% | 96.7% | 95.8% |

| Specimen | PPX | THC | THC 25 | THC 20 | TCA | TRA | MDPV |
|---|---|---|---|---|---|---|---|
| Positive | 95.0% | 95.8% | 94.2% | 91.7% | 95.0% | 93.3% | 94.2% |
| Negative | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Total | 97.5% | 97.9% | 97.1% | 95.8% | 97.5% | 96.7% | 97.1% |

### Analytical Sensitivity

Total 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25%

Cut-Off; +50% Cut-Off were tested using three different lots of each dip card by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, EDDP (Methadone Metabolites), Tricyclic Antidepressants, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, K2 (Synthetic Cannabinoid), Ketamine, Methaqualone, Methadone, Fentanyl, Tramadol, Ethyl Glucuronide, Cotinine, 6-Monoacetylmorphine, Methylenedioxypyrovalerone, Lysergic acid diethylamide, Marijuana and Benzodiazepines. The cut-off value for the dip card is verified.

**Analytical Specificity**

The following table lists compounds that are positively detected in urine by the **One Step Multi-Drug Screen Test Dip Card (Urine)** at 5 minutes.

| Drug | Concentration (ng/mL) |
|---|---|
| **AMPHETAMINE (AMP)** | |
| D-Amphetamine | 1,000 |
| D,L - Amphetamine (Amphetamine Sulfate) | 1,000 |
| Phentermine | 1,250 |
| (+/-)-4-Hydroxyamphetamine HCL | 600 |
| L-Amphetamine | 20,000 |
| 3,4-Methylenedioxyamphetamine HCI (MDA) | 1,500 |
| d-Methamphetamine | >100,000 ng/mL |
| 1-Methamphetamine | >100,000 ng/mL |
| ephedrine | >100,000 ng/mL |
| 3,4-Methylenedioxyethylamphetamine (MDE) | >100,000 ng/mL |
| 3,4-methylenedioxy-methamphetamine (MDMA) | >100,000 ng/mL |
| | |
| **AMPHETAMINE (AMP 500)** | |
| D-Amphetamine | 500 |
| D,L-Amphetamine | 750 |
| L-Amphetamine | 16,000 |
| Phentermine | 650 |
| (+/-)-Methylenedioxyamphetamine (MDA) | 800 |
| d-Methamphetamine | >100,000 |
| 1-Methamphetamine | >100,000 |
| ephedrine | >100,000 |
| 3,4-Methylenedioxyethylamphetamine (MDE) | >100,000 |
| 3,4-methylenedioxy-methamphetamine (MDMA) | >100,000 |
| | |
| **AMPHETAMINE (AMP 300)** | |
| D-Amphetamine | 300 |
| D,L-Amphetamine | 450 |
| L-Amphetamine | 9,000 |
| Phentermine | 450 |
| (+/-)-Methylenedioxyamphetamine (MDA) | 600 |
| | |
| **BARBITURATES (BAR)** | |
| Secobarbital | 300 |
| Amobarbital | 300 |
| Alphenal | 750 |
| Aprobarbital | 250 |
| Butabarbital | 2,500 |
| Butethal | 2,500 |
| Cyclopentobarbital | 500 |
| Pentobarbital | 2,500 |
| Phenobarbital | 25,000 |
| | |
| **BARBITURATES (BAR 200)** | |
| Secobarbital | 200 |
| Amobarbital | 200 |
| Alphenal | 500 |
| Aprobarbital | 200 |
| Butabarbital | 2,000 |
| Butethal | 2,000 |
| Butalbital | 2,000 |

| Drug | Concentration (ng/mL) |
|---|---|
| Cyclopentobarbital | 300 |
| Pentobarbital | 2,000 |
| | |
| **BENZODIAZEPINES (BZO)** | |
| Alprazolam | 200 |
| Bromazepam | 1,560 |
| Chlordiazepoxide HCL | 1,560 |
| Clobazam | 100 |
| Clonazepam | 780 |
| Clorazepate Dipotassium | 200 |
| Delorazepam | 1,560 |
| Desalkylflurazepam | 400 |
| Diazepam | 200 |
| Estazolam | 2,500 |
| Flunitrazepam | 400 |
| a-Hydroxyalprazolam | 1260 |
| (±) Lorazepam | 1,560 |
| RS-Lorazepam glucuronide | 160 |
| Midazolam | 12,500 |
| Nitrazepam | 100 |
| Norchlordiazepoxide | 200 |
| Nordiazepam | 400 |
| Oxazepam | 300 |
| Temazepam | 100 |
| Triazolam | 2,500 |
| | |
| **BENZODIAZEPINES (BZO200)** | |
| Alprazolam | 200 |
| Bromazepam | 1,000 |
| Chlordiazepoxide HCL | 1,000 |
| Clobazam | 80 |
| Clonazepam | 500 |
| Clorazepate Dipotassium | 100 |
| Delorazepam | 1,000 |
| Desalkylflurazepam | 300 |
| Diazepam | 100 |
| Estazolam | 2,000 |
| Flunitrazepam | 300 |
| a-Hydroxyalprazolam | 840 |
| (±) Lorazepam | 1,000 |
| RS-Lorazepam glucuronide | 100 |
| Midazolam | 10,000 |
| Nitrazepam | 100 |
| Norchlordiazepoxide | 100 |
| Nordiazepam | 300 |
| Oxazepam | 200 |
| Temazepam | 800 |
| Triazolam | 2,000 |
| | |
| **BUPRENORPHINE (BUP)** | |
| Buprenorphine | 10 |
| Norbuprenorphine | 20 |
| | |
| **COCAINE (COC)** | |
| Benzoylecogonine | 300 |
| Cocaethylene | 300 |
| Cocaine HCl | 300 |
| | |
| **COCAINE (COC 150)** | |

| Drug | Concentration (ng/mL) |
|---|---|
| Benzoylecogonine | 150 |
| Cocaethylene | 2,500 |
| Cocaine | 500 |
| Ecgonine | 12,500 |
| Ecgonine methylester | 50,000 |
| | |
| **COTININE (COT)** | |
| Cotinine | 200 |
| Nicotine | 6,250 |
| | |
| **MDMA (ECSTASY)** | |
| D,L-3,4-Methylenedioxymethamphetamine (MDMA) | 500 |
| 3,4-Methylenedioxyamphetamine HCI (MDA) | 3,000 |
| 3,4-Methylenedioxyethyla-amphetamine (MDEA) | 300 |
| d-methamphetamine | 2500 |
| d-amphetamine | >100,000 |
| l-amphetamine | >100,000 |
| l-methamphetamine | >100,000 |
| | |
| **ETHYL GLUCURONIDE (EtG 500)** | |
| Ethyl-β-D-glucuronide | 500 |
| Ethyl-β-D-glucuronide-D5 | 500 |
| | |
| **ETHYL GLUCURONIDE (EtG 300)** | |
| Ethyl-β-D-glucuronide | 300 |
| Ethyl-β-D-glucuronide-D5 | 300 |
| | |
| **FENTANYL (FEN)** | |
| Norfentanyl | 20 |
| Fentanyl | 300 |
| | |
| **FENTANYL (FEN20)** | |
| Norfentanyl | 20 |
| Fentanyl | 300 |
| | |
| **FENTANYL (FEN200)** | |
| Norfentanyl | 15 |
| Fentanyl | 200 |
| Sufentanyl | 50,000 |
| Fenfluramine | 50,000 |
| | |
| **FENTANYL (FEN 100)** | |
| Norfentanyl | 10 |
| Fentanyl | 100 |
| Buspirone | >100,000 |
| Sufentanyl | 25,000 |
| Fenfluramine | 25,000 |
| | |
| **KETAMINE (KET)** | |
| Ketamine | 1,000 |
| Norketamine | 3,000 |
| Methoxy-amphetamine | 12,500 |
| Promethazine | 25,000 |
| 4-hydroxyphenyl cyclohexyl piperidine | 50,000 |
| | |
| **KETAMINE (KET 100)** | |
| Ketamine | 100 |
| Norketamine | 100 |
| Methoxy-amphetamine | 1,250 |

| Drug | Concentration (ng/mL) |
|---|---|
| Promethazine | 2,500 |
| 4-hydroxyphenyl cyclohexyl piperidine | 5,000 |
| | |
| **LYSERGIC ACID DIETHYLAMIDE (LSD)** | |
| D-lysergic acid diethylamide | 20 |
| Fentanyl | 75 |
| Norfentanyl | 300 |
| | |
| **MARIJUANA (THC)** | |
| Delta-9-Tetrahydrocannabinol | 50,000 |
| 11-nor-delta-9-THC-carboxyglucuronide | 75 |
| (-)-11-nor-9-carboxy-delta9-THC | 75 |
| 11-Nor-$\Delta^9$-Tetrahydrocannabinol | 50 |
| 11-Hydroxy-$\Delta^9$-Tetrahydrocannabinol | 5,000 |
| 11-Nor-$\Delta^8$-Tetrahydrocannabinol | 50 |
| $\Delta^8$-THC-COOH | 50,000 |
| | |
| **MARIJUANA (THC 25)** | |
| Delta-9-Tetrahydrocannabinol | 25,000 |
| 11-nor-delta-9-THC-carboxyglucuronide | 37.5 |
| (-)-11-nor-9-carboxy-delta9-THC | 37.5 |
| 11-Nor-$\Delta^9$-Tetrahydrocannabinol | 25 |
| 11-Hydroxy-$\Delta^9$-Tetrahydrocannabinol | 2,500 |
| 11-Nor-$\Delta^8$-Tetrahydrocannabinol | 25 |
| $\Delta^8$-THC-COOH | 25,000 |
| | |
| **MARIJUANA (THC 20)** | |
| Delta-9-Tetrahydrocannabinol | 20,000 |
| 11-nor-delta-9-THC-carboxyglucuronide | 30 |
| (-)-11-nor-9-carboxy-delta9-THC | 30 |
| 11-Nor-$\Delta^9$-Tetrahydrocannabinol | 20 |
| 11-Hydroxy-$\Delta^9$-Tetrahydrocannabinol | 2,000 |
| 11-Nor-$\Delta^8$-Tetrahydrocannabinol | 20 |
| $\Delta^8$-THC-COOH | 20,000 |
| | |
| **METHADONE (MTD)** | |
| Methadone | 300 |
| Doxylamine | 5,000 |
| | |
| **EDDP (Methadone Metabolites)** | |
| EDDP | 300 |
| Disopyramide | 50,000 |
| Methadone | >100,000 |
| EMDP | 500 |
| | |
| **EDDP100 (Methadone Metabolites)** | |
| EDDP | 100 |
| Disopyramide | 20,000 |
| Methadone | >100,000 |
| EMDP | 200 |
| | |
| **METHAMPHETAMINE (mAMP)** | |
| D-Methamphetamine | 1,000 |
| (+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA) | 20,000 |
| Procaine (Novocaine) | 60,000 |
| Trimethobenzamide | 20,000 |
| Methamphetamine | 1,000 |
| Ranitidine (Zantac) | 50,000 |
| (+/-) 3,4-Methylenedioxymethamphetamine (MDMA) | 2,500 |

| Drug | Concentration (ng/mL) |
|---|---|
| Chloroquine | 50,000 |
| Ephedrine | 100,000 |
| Fenfluramine | 50,000 |
| p-Hydroxymethamphetamine | 10,000 |
| | |
| **METHAMPHETAMINE (MET 500)** | |
| p-Hydroxymethamphetamine | 15,000 |
| l-Methamphetamine | 4,000 |
| Mephentermine | 25,000 |
| d,l-Amphetamine | 75,000 |
| (1R,2S)-(-)-Ephedrine | 50,000 |
| β-Phenylethylamine | 75,000 |
| d-Methamphetamine | 500 |
| 3,4-Methylenedioxymethamphetamine (MDMA) | 1,000 |
| d-Amphetamine | 50,000 |
| Chloroquine | 12,500 |
| (+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA) | 20,000 |
| Procaine (Novocaine) | 50,000 |
| Trimethobenzamide | 20,000 |
| Ranitidine (Zantac) | 50,000 |
| Fenfluramine | 50,000 |
| | |
| **METHAMPHETAMINE (MET 300)** | |
| p-Hydroxymethamphetamine | 10,000 |
| l-Methamphetamine | 3,000 |
| Mephentermine | 15,000 |
| d,l-Amphetamine | 50,000 |
| (1R,2S)-(-)-Ephedrine | 50,000 |
| β-Phenylethylamine | 50,000 |
| d-Methamphetamine | 300 |
| 3,4-Methylenedioxymethamphetamine (MDMA) | 1,000 |
| d-Amphetamine | 30,000 |
| Chloroquine | 7,500 |
| (+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA) | 12,000 |
| Procaine (Novocaine) | 30,000 |
| Trimethobenzamide | 12,000 |
| Ranitidine (Zantac) | 30,000 |
| Fenfluramine | 30,000 |
| | |
| **METHAQUALONE (MQL)** | |
| Methaqualone | 300 |
| | |
| **METHYLENEDIOXYPYROVALERONE (MDPV)** | |
| 3,4-Methylenedioxypyrovalerone | 1,000 |
| Ethylone HCl | 1,200 |
| Methylone | 50,000 |
| Pyrovalerone | 50,000 |
| | |
| **6-MONOACETYLMORPHINE (6-MAM)** | |
| 6-Moonacetylmorphine | 10 |
| Morphine | >500,000 |
| Codeine | >600,000 |
| Dextromethorphan | >100,000 |
| Dihydrocodeine | >100,000 |
| Heroin HCl | 250 |
| Hydrocodone | >100,000 |
| Hydromorphone | >100,000 |
| Imipramine | >100,000 |
| Levorphanol | >10,000 |

| Drug | Concentration (ng/mL) |
|---|---|
| NorMeperidine | >10,000 |
| Normorphine | >100,000 |
| Nalorphine | >100,000 |
| Naloxone | >100,000 |
| Naltrexone | >100,000 |
| Norcodeine | >100,000 |
| Oxycodone | >100,000 |
| Oxymorphone | >100,000 |
| | |
| **MORPHINE (MOP)** | |
| Morphine | 300 |
| O6-Acetylmorphine | 400 |
| Codeine | 300 |
| EthylMorphine | 100 |
| Heroin | 600 |
| Hydromorphone | 500 |
| Hydrocodone | 50,000 |
| Levorphanol | 1,500 |
| Oxycodone | 30,000 |
| Procaine | 15,000 |
| Thebaine | 6,240 |
| | |
| **MORPHINE (OPI, MOP2000)** | |
| Morphine | 2,000 |
| O6-Acetylmorphine | 2,500 |
| Codeine | 1,000 |
| EthylMorphine | 250 |
| Heroin | 5,000 |
| Hydromorphone | 2,500 |
| Hydrocodone | 5,000 |
| Oxycodone | 75,000 |
| Thebaine | 13,000 |
| | |
| **OXYCODONE (OXY)** | |
| Naloxone hydrochloride | 10,000 |
| Naltrexone hydrochloride | 50,000 |
| Oxycodone | 100 |
| Hydrocodone | 5,000 |
| Hydromorphone | 5,000 |
| Oxymorphone-D3 | 5,000 |
| Oxymorphone | 200 |
| N-Benzylisopropylamine | 2,500 |
| | |
| **PHENCYCLIDINE (PCP)** | |
| Phencyclidine | 25 |
| 4-Hydroxy Phencyclidine | 90 |
| | |
| **PROPOXYPHENE (PPX)** | |
| Norpropoxyphene | 300 |
| d-Propoxyphene | 300 |
| | |
| **K2 (SYNTHETIC CANNABINOID)** | |
| JWH-018 5-Pentanoic acid metabolite | 50 |
| JWH-018 5-Hydroxypentyl metabolite | 500 |
| JWH-018 4-Hydroxypentyl metabolite | 400 |
| JWH-018 N-(4-hydroxypentyl) metabolite solution | 5,000 |
| JWH-019 5-hydroxyhexylmetabolite | <10,000 |
| JWH-019 6-Hydroxyhexyl | 5,000 |
| JWH-073 4-butanoic acid metabolite | 50 |

| Drug | Concentration (ng/mL) |
|---|---|
| JWH-073 4-Hydroxybutyl metabolite | 500 |
| JWH-210 5-Hydroxypentyl metabolite solution | <10,000 |
| JWH-122 5-Hydroxypentyl metabolite solution | <10,000 |
| Spice Cannabinoid Mix 3 solution | <10,000 |
| JWH-122 4-Hydroxypentyl metabolite solution | <10,000 |
| JWH-122 4-Hydroxypentyl metabolite-D5 solution | <10,000 |
| JWH-019 5-hydroxyhexylmetabolite | <10,000 |
| JWH-018 N-(4-hydroxypentyl) metabolite solution | <10,000 |
| JWH-073 N-(3-Hydroxybutyl) metabolite solution | <10,000 |
| | |
| **K2 (SYNTHETIC CANNABINOID) 25 ng/mL** | |
| JWH-018 5-Pentanoic acid metabolite | 25 |
| JWH-018 5-Hydroxypentyl metabolite | 250 |
| JWH-018 4-Hydroxypentyl metabolite | 200 |
| JWH-018 N-(4-hydroxypentyl) metabolite solution | 2,500 |
| JWH-019 5-hydroxyhexylmetabolite | <10,000 |
| JWH-019 6-Hydroxyhexyl | 2,500 |
| JWH-073 4-butanoic acid metabolite | 25 |
| JWH-073 4-Hydroxybutyl metabolite | 250 |
| JWH-210 5-Hydroxypentyl metabolite solution | <10,000 |
| JWH-122 5-Hydroxypentyl metabolite solution | <10,000 |
| Spice Cannabinoid Mix 3 solution | <10,000 |
| JWH-122 4-Hydroxypentyl metabolite solution | <10,000 |
| JWH-122 4-Hydroxypentyl metabolite-D5 solution | <10,000 |
| JWH-019 5-hydroxyhexylmetabolite | <10,000 |
| JWH-018 N-(4-hydroxypentyl) metabolite solution | <10,000 |
| JWH-073 N-(3-Hydroxybutyl) metabolite solution | <10,000 |
| | |
| **TRAMADOL (TRA )** | |
| Tramadol | 200 |
| N-desmethyl-tramadol | 500 |
| O-desmethyl-tramadol | 20,000 |
| | |
| **Tricyclic Antidepressants (TCA)** | |
| Nortriptyline | 1,000 |
| Amitriptyline | 1,500 |
| Clomipramine | 50,000 |
| Desipramine | 5,000 |
| Doxepine | 10,000 |
| Imipramine | 10,000 |
| Maprotiline | 100,000 |
| Nordoxepin | 10,000 |
| Promazine | 50,000 |
| Promethazine | 2,500 |
| Trimipramine | 50,000 |
| Cyclobenzaprine Hydrochloride | 5,000 |
| Norclomipramine | 50,000 |

## Precision

This study is performed 2 runs/day and lasts 25 days for each format with three lots. Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day). A total of 50 determinations by each operator, at each concentration, were made. The results are given below:

| Drug Conc. (Cut-off range) | AMP | | AMP 500 | | AMP 300 | | BAR | | BAR 200 | | BZO | | BZO 200 | | BUP | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + |
| 0% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -75% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -50% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -25% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| Cut-off | 20 | 30 | 20 | 30 | 22 | 28 | 23 | 27 | 23 | 27 | 18 | 32 | 24 | 26 | 28 | 22 |
| +25% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |
| +50% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |
| +75% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |
| +100% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |

| Drug Conc. (Cut-off range) | COC | | COC150 | | COT | | EDDP | | EDDP 100 | | ETG | | ETG 300 | | FEN | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + |
| 0% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -75% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -50% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -25% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 41 | 9 | 44 | 6 | 42 | 8 | 50 | 0 |
| Cut-off | 20 | 30 | 24 | 26 | 20 | 30 | 21 | 29 | 30 | 20 | 23 | 27 | 23 | 27 | 22 | 28 |
| +25% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 3 | 47 | 8 | 42 | 4 | 46 | 0 | 50 |
| +50% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |
| +75% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |
| +100% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |

| Drug Conc. (Cut-off range) | FEN 200 | | FEN 100 | | FEN 20 | | K2 | | K2 25 | | KET | | KET 100 | | MET | | MET 500 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + |
| 0% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -75% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -50% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -25% Cut-off | 46 | 4 | 43 | 7 | 50 | 0 | 50 | 0 | 50 | 0 | 45 | 5 | 44 | 6 | 50 | 0 | 50 | 0 |
| Cut-off | 28 | 22 | 20 | 30 | 22 | 28 | 18 | 32 | 22 | 28 | 18 | 32 | 30 | 20 | 24 | 26 | 25 | 25 |
| +25% Cut-off | 5 | 45 | 2 | 48 | 0 | 50 | 0 | 50 | 0 | 50 | 6 | 44 | 3 | 47 | 0 | 50 | 0 | 50 |
| +50% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |
| +75% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |
| +100% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |

| Drug Conc. (Cut-off range) | OXY | | MET 300 | | MDMA | | MOP | | MQL | | 6-MAM | | MTD | | OPI | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | - | - | + | - | + | - | + | - | + |
| 0% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 50 | 50 | 0 | 50 | 0 | 50 | 0 |
| -75% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 50 | 50 | 0 | 50 | 0 | 50 | 0 |
| -50% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 50 | 50 | 0 | 50 | 0 | 50 | 0 |
| -25% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 48 | 50 | 50 | 0 | 50 | 0 | 50 | 0 |
| Cut-off | 24 | 26 | 25 | 25 | 24 | 26 | 22 | 28 | 24 | 22 | 22 | 27 | 28 | 22 | 22 | 28 |
| +25% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 6 | 0 | 5 | 45 | 0 | 50 | 0 | 50 |
| +50% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 0 | 0 | 50 | 0 | 50 | 0 | 50 |
| +75% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 0 | 0 | 50 | 0 | 50 | 0 | 50 |
| +100% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 0 | 0 | 50 | 0 | 50 | 0 | 50 |

| Drug Conc. (Cut-off range) | PCP | | PPX | | THC | | THC 25 | | THC 20 | | TCA | | TRA | | LSD | | MDPV | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + |
| 0% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -75% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -50% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -25% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 47 | 3 | 44 | 6 | 48 | 2 |
| Cut-off | 22 | 28 | 26 | 24 | 20 | 30 | 23 | 27 | 25 | 25 | 22 | 28 | 25 | 25 | 21 | 29 | 24 | 26 |
| +25% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 1 | 49 | 5 | 45 | 7 | 43 |
| +50% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |
| +75% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |
| +100% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |

## Effect of Urinary Specific Gravity

Twelve (12) urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The **One Step Multi-Drug Screen Test Dip Card (Urine)** was tested in duplicate using drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

## Effect of Urinary pH

The pH of an aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above Cutoff levels. The spiked, pH-adjusted urine was tested with The **One Step Multi-Drug Screen Test Dip Card (Urine)**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

## Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, EDDP (Methadone Metabolites), Tricyclic Antidepressants, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, K2(Synthetic Cannabinoid), Ketamine, Methaqualone, Methadone, Fentanyl, Tramadol, Ethyl Glucuronide, Cotinine, 6-Monoacetylmorphine, Methylenedioxypyrovalerone, Lysergic acid diethylamide, Marijuana and Benzodiazepines positive urine. The following compounds show no cross-reactivity when tested with the **One Step Multi-Drug Screen Test Dip Card (Urine)** at a concentration of 100 μg/mL.

### Non Cross-Reacting Compounds

| | | | |
|---|---|---|---|
| Acetophenetidin | Cortisone | Pseudoephedrine | Quinidine |
| N-Acetylprocainamide | Creatinine | Kynurenic Acid | Quinine |
| Acetylsalicylic acid | Dexamethasone | Labetalol | Salicylic acid |
| Amiloride | Dextromethorphan | Loperamide | Serotonin |
| Amoxicillin | Desipramine | Meprobamate | Sulfamethazine |
| Ampicillin | Diflunisal | Methoxyphenamine | Sulindac |
| l-Ascorbic acid | Digoxin | Methylphenidate | Tetracycline |
| Apomorphine | Droperidol | Nalidixic acid | Tetrahydrocortisone, |
| Aspartame | Ethyl-p-aminobenzoate | Naproxen | 3-Acetate |
| Atropine | Ethopropazine | Niacinamide | Theobromine |
| Benzilic acid | Estrone-3-sulfate | Nifedipine | Tolazamide |
| p-Aminobenzoic Acid | Erythromycin | Norethindrone | Tetrahydrozoline |
| Bilirubin | Fenoprofen | Noscapine | Thiamine |
| Beclomethasone | Furosemide | Octopamine | Thioridazine Hydrochloride |
| Caffeine | Gentisic acid | Oxalic acid | D/L-Tyrosine |
| Cannabidiol | Hemoglobin | Oxyphenbutazone | Tolbutamide |
| Carbamazepine | Hydralazine | Oxymetazoline | Triamterene |
| Chloramphenicol | Hydrochlorothiazide | Papaverine | Trifluoperazine |
| Chlorothiazide | Hydrocortisone | Paclitaxel | Trimethoprim |
| Chlorpheniramine | α-Hydroxyhippuric acid | Perphenazine | D,L-Tryptophan |
| Chlorpromazine | Hydroxyprogesterone | Phenelzine | Uric acid |
| Cholesterol | Isoproterenol-(+/-) | Prednisone | Verapamil |
| Clonidine | Isoxsuprine | Prilocaine | Zomepirac |

## BIBLIOGRAPHY


1. *Stewart DJ, Inaba T, Lucassen M, Kalow W. Clin. Pharmacol. Ther. April 1979; 25 ed: 464, 264-8.*
2. *Ambre J. J. Anal. Toxicol. 1985; 9:241.*
3. *Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.*
4. *Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.*
5. *FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.*


## INDEX OF SYMBOLS

| | | | | | |
|---|---|---|---|---|---|
| | Consult instructions for use | Σ | Tests per kit | EC REP | Authorized Representative |
| IVD | For *in vitro* diagnostic use only | | Use by | | Do not reuse |
| 2°C 30°C | Store between 2~30°C | LOT | Lot Number | REF | Catalog# |

Zhejiang Orient Gene Biotech Co., Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

REF GBDUA-1X4

Revision Date: 2022-05-31
B21769-03

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Product Service

# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

## No. G10 113499 0001 Rev. 00

**Manufacturer:**

**Global Medikit Limited**
Khasra no. 323 (MI), Central Hope Town, Camp Road, Selaqui
Dehradun, Uttarakhand 248197
INDIA

**SRN Manufacturer:** IN-MF-000013635

**Authorized Representative:**

Obelis s.a.
Bd. Général Wahis 53, 1030 Brussels, BELGIUM

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 113499 0001 Rev. 00

**Report No.:** TPS0445

**Valid from:** 2023-02-16
**Valid until:** 2028-02-15

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2023-02-16


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Product Service

# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

## No. G10 113499 0001 Rev. 00

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | A0601010401 - THORACIC DRAINAGES (STRAIGHT AND ANGLED) |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | R030102 - AIR/OXYGEN MASKS AND NASAL CANNULAS |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | R030103 - AEROSOL THERAPY MASKS AND SYSTEMS |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | F020180 - ARTERIOVENOUS DIALYSIS LINES FOR HAEMODIALYSIS - HAEMOFILTRATION - HAEMODIAFILTRATION - ACCESSORIES |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | A010401 - ARTERIOVENOUS FISTULA NEEDLES |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | A030401 - INFUSION KITS (INCLUDING THOSE VIA PUMP), SINGLE-USE |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | A060199 - SURGICAL DRAINAGE SYSTEMS - OTHER |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | G020201 - NASOGASTRIC INTESTINAL TUBES |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | R05010102 - RESPIRATORY SUCTION PROBES WITH CONTROL HOLE |
| **Intended Purpose:** | - |


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# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

## No. G10 113499 0001 Rev. 00

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | U010105 - URETHRAL PROSTATIC AND BLADDER CATHETERS, NELATON |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | R050101 - RESPIRATORY SUCTION PROBES |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | G020299 - GASTROINTESTINAL FEEDING/ASPIRATION TUBES - OTHER |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | A0703 - STOPCOCKS |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | A030499 - ADMINISTRATION KITS - OTHER |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | C010101 - PERIPHERAL I.V. CATHETERS |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | A0302 - EXTENSION LINES |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | A030104 - FLOW REGULATORS |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | R010301 - ENDOTRACHEAL TUBES, CUFFLESS |
| **Intended Purpose:** | - |


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# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

## No. G10 113499 0001 Rev. 00

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | R010302 - ENDOTRACHEAL TUBES, CUFFED |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | IIa |
| **Device Group:** | G0202 - GASTROINTESTINAL FEEDING/ASPIRATION TUBES |
| **Intended Purpose:** | - |

| | |
|---|---|
| **The validity of this certificate depends on conditions and/or is limited to the following:** | - |


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Product Service

# EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

## No. G70 113499 0004 Rev. 00

**Manufacturer:**

**Global Medikit Limited**
Khasra no. 323 (MI), Central Hope Town, Camp Road, Selaqui
Dehradun, Uttarakhand 248197
INDIA

**SRN Manufacturer:** IN-MF-000013635

**Authorized Representative:**

Obelis s.a.
Bd. Général Wahis 53, 1030 Brussels, BELGIUM

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 113499 0004 Rev. 00

**Report No.:** 713223667

**Valid from:** 2023-02-07
**Valid until:** 2028-02-06

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2023-02-07


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# EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

## No. G70 113499 0004 Rev. 00

**Classification:** III

**Device Group:** A01030101 - SPINAL ANAESTHESIA NEEDLES AND KITS

**Basic UDI-DI:** 8903545GMLSPN002PS

**Intended Purpose:** Spinal Needle (Quincke Bevel and Pencil Point) are intended for injection of local anesthetics into the subarachnoid space to provide spinal anesthesia for pain management or to facilitate CSF sample collection for diagnostic purposes (lumbar puncture).

**Device(s):** Spinal Needles: Quincke Bevel without Introducer Needle, Pencil Point without Introducer Needle, Pencil Point with Introducer Needle Trade names: Medispine and Glospine. Each trade name covers in total 60 device variants/models. For device variants/models and parameters please see model list at the end of this certificate.

**The validity of this certificate depends on conditions and/or is limited to the following:** --

| Gauge Size | Color code | GLOSPINE | | | MEDISPINE | | |
|---|---|---|---|---|---|---|---|
| | | Quincke Bevel without introducer needle | Pencil Point without introducer needle | Pencil Point with introducer needle | Quincke Bevel without introducer needle | Pencil Point without introducer needle | Pencil Point with introducer needle |
| Reference no. (Spinal needle – 70 mm) | | | | | | | |



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# EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

## No. G70 113499 0004 Rev. 00

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 18G | Pink | 643118G | 655118G | - | 643118B | 655118B | - |
| 19G | Cream | 643119G | 655119G | - | 643119B | 655119B | - |
| 20G | Yellow | 643120G | 655120G | - | 643120B | 655120B | - |
| 21G | Deep Green | 643121G | 655121G | - | 643121B | 655121B | - |
| 22G | Black | 643122G | - | 643122GP | 643122B | - | 643122BG |
| 23G | Deep Blue | 643123G | - | 643123GP | 643123B | - | 643123BG |
| 24G | Medium Purple | 643124G | - | 643124GP | 643124B | - | 643124BG |
| 25G | Orange | 643125G | - | 643125GP | 643125B | - | 643125BG |
| 26G | Brown | 643126G | - | 643126GP | 643126B | - | 643126BG |
| 27G | Medium Grey | 643127G | - | 643127GP | 643127B | - | 643127BG |
| **Reference no. (Spinal needle – 90 mm)** | | | | | | | |


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# EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

## No. G70 113499 0004 Rev. 00

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 18G | Pink | 643018G | 655018G | - | 643018B | 655018B | - |
| 19G | Cream | 643019G | 655019G | - | 643019B | 655019B | - |
| 20G | Yellow | 643020G | 655020G | - | 643020B | 655020B | - |
| 21G | Deep Green | 643021G | 655021G | - | 643021B | 655021B | - |
| 22G | Black | 643022G | - | 643022GP | 643022B | - | 643022BG |
| 23G | Deep Blue | 643023G | - | 643023GP | 643023B | - | 643023BG |
| 24G | Medium Purple | 643024G | - | 643024GP | 643024B | - | 643024BG |
| 25G | Orange | 643025G | - | 643025GP | 643025B | - | 643025BG |
| 26G | Brown | 643026G | - | 643026GP | 643026B | - | 643026BG |
| 27G | Medium Grey | 643027G | - | 643027GP | 643027B | - | 643027BG |
| **Reference no. (Spinal needle – 120 mm)** | | | | | | | |
| 18G | Pink | 643218G | 655218G | - | 643218B | 655218B | - |
| 19G | Cream | 643219G | 655219G | - | 643219B | 655219B | - |
| 20G | Yellow | 643220G | 655220G | - | 643220B | 655220B | - |
| 21G | Deep Green | 643221G | 655221G | - | 643221B | 655221B | - |
| 22G | Black | 643222G | - | 643222GP | 643222B | - | 643222BG |
| 23G | Deep Blue | 643223G | - | 643223GP | 643223B | - | 643223BG |
| 24G | Medium Purple | 643224G | - | 643224GP | 643224B | - | 643224BG |
| 25G | Orange | 643225G | - | 643225GP | 643225B | - | 643225BG |
| 26G | Brown | 643226G | - | 643226GP | 643226B | - | 643226BG |
| 27G | Medium Grey | 643227G | - | 643227GP | 643227B | - | 643227BG |


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# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

## No. G11 113499 0002 Rev. 00

**Manufacturer:** **Global Medikit Limited**
Khasra no. 323 (MI), Central Hope Town, Camp Road, Selaqui
Dehradun, Uttarakhand 248197
INDIA

**SRN Manufacturer:** IN-MF-000013635

**Authorized Representative:**
Obelis s.a.
Bd. Général Wahis 53, 1030 Brussels, BELGIUM

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G11 113499 0002 Rev. 00

**Report No.:** TPS0445

**Valid from:** 2023-02-15
**Valid until:** 2028-02-14

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2023-02-15


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TÜV SÜD Product Service

# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

## No. G11 113499 0002 Rev. 00

| | |
|---|---|
| **Classification:** | I |
| **Device Group:** | A07050201 - CAPS OR OBTURATORS, PERFORABLE WITH NEEDLE<br>A07050202 - CAPS OR OBTURATORS, PERFORABLE WITHOUT NEEDLE |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization |
| **Classification:** | I |
| **Device Group:** | A070501 - CAPS OR OBTURATORS, NON-PERFORABLE |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization |
| **Classification:** | I |
| **Device Group:** | R050103 - MUCOUS ASPIRATORS |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization |
| **Classification:** | I |
| **Device Group:** | A060303 - URINE COLLECTION SYSTEMS AND BAGS, SINGLE-USE |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization |
| **Classification:** | I |
| **Device Group:** | A060303 - URINE COLLECTION SYSTEMS AND BAGS, SINGLE-USE |
| **Device Properties:** | MDS 1005.1 - Ethylene Oxide sterilization<br>MDS 1010 - Devices with a measuring function |
| **The validity of this certificate depends on conditions and/or is limited to the following:** | - |


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The better life

# The better life

www.globalmedikit.in

# Gloflon®

## I.V. Catheter with Injection Valve and Wings

**Posseses all features of a standard intravenous catheter.**

- Stainless steel, silicone tipped needle for smooth penetration.
- Injection port with one way silicone injection valve.
- Specially designed protection cap with a recessed plug to cover
- the injection port and minimize contamination.
- Angled and grooved wings for secure fixation.
- Radio-opaque lines for accurate radiographic detection.
- Luer cap for blocking the catheter when not in use.
- 6% luer taper for compatibility with all standard devices.
- Disposable, sterile and non-pyrogenic.

### Technical Specifications

| | | Catheter | | | | | |
|---|---|---|---|---|---|---|---|
| Gauge | Colour Code | Ext. Dia. (mm.) | Length (mm.) | Flow Rate (ml./min.) | Ref. No. Radiopaque | Ref. No. Clear | Qty. in carton Inner/ Outer |
| 14 | Orange | 2.1 | 45 | 300 | 40214BBC | 40214ABC | 100/1000 |
| 16 | Grey | 1.8 | 45 | 200 | 40216BBC | 40216ABC | 100/1000 |
| 17 | White | 1.5 | 45 | 140 | 40217BBC | 40217ABC | 100/1000 |
| 18 | Green | 1.3 | 45 | 90 | 40218BBC | 40218ABC | 100/1000 |
| 20 | Pink | 1.1 | 33 | 61 | 40220BBC | 40220ABC | 100/1000 |
| 22 | Blue | 0.9 | 25 | 36 | 40222BBC | 40222ABC | 100/1000 |
| 24 | Yellow | 0.7 | 19 | 15 | 40224BBC | 40224ABC | 100/1000 |
| 26 | Purple | 0.6 | 19 | 13 | 40226BBC | 40226ABC | 100/1000 |

# Glothin®

## I.V. Catheter with Injection Valve and Wings

- A specially designed injection port cap which has a recessed plug and a protective skirt to minimize contamination.
- Disposable, sterile, non-pyrogenic.
- Sealed blister packing.

### Technical Specifications

| | | Catheter | | | | |
|---|---|---|---|---|---|---|
| Gauge | Colour Code | Ext. Dia. (mm.) | Length (mm.) | Flow Rate (ml./min.) | Ref. No. Clear | Qty. in carton Inner/ Outer |
| 14 | Orange | 2.1 | 45 | 300 | 4100142G | 100/1000 |
| 16 | Grey | 1.8 | 45 | 200 | 4100162G | 100/1000 |
| 17 | White | 1.5 | 45 | 140 | 4100172G | 100/1000 |
| 18 | Green | 1.3 | 45 | 90 | 4100182G | 100/1000 |
| 20 | Pink | 1.1 | 33 | 61 | 4100202G | 100/1000 |
| 22 | Blue | 0.9 | 25 | 36 | 4100222G | 100/1000 |
| 24 | Yellow | 0.7 | 19 | 15 | 4100242G | 100/1000 |
| 26 | Purple | 0.6 | 19 | 13 | 4100262G | 100/1000 |

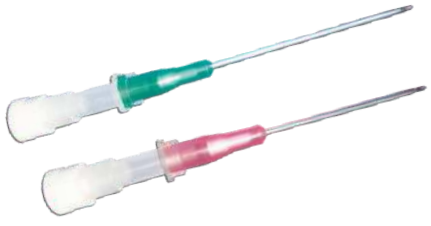
Infusion

# Glocan Alpha®

## I.V. Catheter without Injection Valve and without Wings

**I.V. Catheter with a unique design to minimize transmission of infection in patients with a large infective load.**

- Streamlined, sleek design for easy orientation and insertion.
- Stainless steel, silicone tipped needle.
- Long and broad hub for good grip and control.
- Colour coded body.
- Disposable, sterile and non-pyrogenic .



### Technical Specifications

| | | Catheter | | | | |
|---|---|---|---|---|---|---|
| Gauge | Colour Code | Ext. Dia. (mm.) | Length (mm.) | Flow Rate (ml./min.) | Ref. No. Radiopaque | Qty. in carton Inner/ Outer |
| 14 | Orange | 2.1 | 45 | 300 | 4110142G | 100/1000 |
| 16 | Grey | 1.8 | 45 | 200 | 4110162G | 100/1000 |
| 17 | White | 1.5 | 45 | 140 | 4110172G | 100/1000 |
| 18 | Green | 1.3 | 45 | 90 | 4110182G | 100/1000 |
| 20 | Pink | 1.1 | 33 | 61 | 4110202G | 100/1000 |
| 22 | Blue | 0.9 | 25 | 36 | 4110222G | 100/1000 |
| 24 | Yellow | 0.7 | 19 | 15 | 4110242G | 100/1000 |
| 26 | Purple | 0.6 | 19 | 13 | 4110262G | 100/1000 |

# Gloflon Safety®

## Safety I. V. Catheter with Injection Valve and Wings

**I.V. Catheter with injection valve and wings with added safety feature for prevention of needle stick injury.**

- Safety feature for complete protection from needle stick injury.
- Passive, irreversible activation of safety mechanism.
- No change in insertion technique required.
- Stainless steel, silicone tipped needle for smooth penetration.
- Injection port with one way silicone injection valve.
- Specially designed protection cap with a recessed plug to cover the injection port and minimize contamination.
- Angled and grooved wings for secure fixation.
- Radio-opaque lines for accurate radiographic detection.
- Luer cap for blocking the catheter when not in use.
- 6% luer taper for compatibility with all standard devices.
- Disposable, sterile and non-pyrogenic.

### Technical Specifications

| | | Catheter | | | | |
|---|---|---|---|---|---|---|
| Gauge | Colour Code | Ext. Dia. (mm.) | Length (mm.) | Flow Rate (ml./min.) | Ref. No. Radiopaque | Qty. in carton Inner/ Outer |
| 14 | Orange | 2.1 | 45 | 300 | 4580142G | 100/1000 |
| 16 | Grey | 1.8 | 45 | 200 | 4580162G | 100/1000 |
| 17 | White | 1.5 | 45 | 140 | 4580172G | 100/1000 |
| 18 | Green | 1.3 | 45 | 90 | 4580182G | 100/1000 |
| 20 | Pink | 1.1 | 33 | 61 | 4580202G | 100/1000 |
| 22 | Blue | 0.9 | 25 | 36 | 4580222G | 100/1000 |
| 24 | Yellow | 0.7 | 19 | 15 | 4580242G | 100/1000 |
| 26 | Purple | 0.6 | 19 | 13 | 4580262G | 100/1000 |

# Glofancie®

## I.V. Catheter with Wings for Neonates

**Miniature IV catheter with a small, fine and smooth design, especially for use in neonates (children below 1 month of age).**

- Small wings and absence of injection port permits easy handling.
- Large internal diameter for increased flow rate and reduced peel back effect.
- Siliconized needle tip for atraumatic tissue penetration.
- Transparent flashback chamber for easy visualization of blood.
- Available in size 26G.
- Disposable, sterile and non-pyrogenic.
- Sealed blister packing.

### Technical Specifications

| | | Catheter | | | | | |
|---|---|---|---|---|---|---|---|
| Gauge | Colour Code | Ext. Dia. (mm.) | Length (mm.) | Flow Rate (ml./min.) | Ref. No. Radiopaque | Ref. No. Clear | Qty. in carton Inner/ Outer |
| 26 | Purple | 0.6 | 19 | 13 | 40426AB | 40426BB | 100/1000 |

# Gloneo®

## I.V. Catheter with Wings for Neonates

**Miniature IV catheter with a small, fine and smooth design for use in infants (children below 1 year of age) and neonates (children below 1 month of age).**

- Small wings and absence of injection port permits easy handling.
- Large internal diameter for increased flow rate and reduced peel back effect.
- Siliconized needle tip for atraumatic tissue penetration.
- Transparent flashback chamber for easy visualization of blood.
- Available in size 24G.
- Disposable, sterile and non-pyrogenic.
- Sealed blister packing.

### Technical Specifications

| | | Catheter | | | | | |
|---|---|---|---|---|---|---|---|
| Gauge | Colour Code | Ext. Dia. (mm.) | Length (mm.) | Flow Rate (ml./min.) | Ref. No. Radiopaque | Ref. No. Clear | Qty. in carton Inner/ Outer |
| 24 | Yellow | 0.7 | 19 | 15 | 40424BB | 40424AB | 100/1000 |

# Glocath®

## I.V. Catheter with an integrated three-way stopcock

**Ports of the stopcock can be utilized for attaching additional stopcocks for multiple infusion therapy.**

- Colour coded tap for easy identification.
- Flexible wings with suture holes for secure fixation.
- Luer lock stoppers to prevent contamination.
- 360° rotation of the tap without limitation.
- Rigid and sturdy design for longevity.
- Female luers with 6% taper for compatibility with all standard devices.
- Disposable, sterile and non-pyrogenic.
- Sealed blister packing.

### Technical Specifications

| | | Catheter | | | | |
|---|---|---|---|---|---|---|
| Gauge | Colour Code | Ext. Dia. (mm.) | Length (mm.) | Flow Rate (ml./min.) | Ref. No. Radiopaque | Qty. in carton Inner/ Outer |
| 16 | Grey | 1.8 | 45 | 200 | 40316BBC | 30/300 |
| 18 | Green | 1.3 | 45 | 90 | 40318BBC | 30/300 |
| 20 | Pink | 1.1 | 33 | 61 | 40320BBC | 30/300 |
| 22 | Blue | 0.9 | 25 | 36 | 40322BBC | 30/300 |

# Glocan™

## I.V. Catheter without Injection Valve and with Wings

**I.V. Catheter useful in patients carrying highly infective diseases to minimize transmission of infection.**

- Projection on main body for two point grip and easy insertion.
- Streamlined design provides minimum area of contact with the body.
- Maximum needle catheter clearance for minimal peel back effect .

### Technical Specifications

| | | Catheter | | | | | |
|---|---|---|---|---|---|---|---|
| Gauge | Colour Code | Ext. Dia. (mm.) | Length (mm.) | Flow Rate (ml./min.) | Ref. No. Radiopaque | Ref. No. Clear | Qty. in carton Inner/ Outer |
| 14 | Orange | 2.1 | 45 | 300 | 4030142G | 4031142G | 100/1000 |
| 16 | Grey | 1.8 | 45 | 200 | 4030162G | 4031162G | 100/1000 |
| 17 | White | 1.5 | 45 | 140 | 4030172G | 4031172G | 100/1000 |
| 18 | Green | 1.3 | 45 | 90 | 4030182G | 4031182G | 100/1000 |
| 20 | Pink | 1.1 | 33 | 61 | 4030202G | 4031202G | 100/1000 |
| 22 | Blue | 0.9 | 25 | 36 | 4030222G | 4031222G | 100/1000 |
| 24 | Yellow | 0.7 | 19 | 15 | 4030242G | 4031242G | 100/1000 |
| 26 | Purple | 0.6 | 19 | 13 | 4030262G | 4031262G | 100/1000 |

Infusion

# Gloflex®

## Three-way stopcock

**Three way stopcock made of polycarbonate**

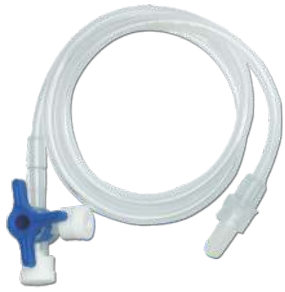
- Multiple channels for multiple infusion therapy.
- Designed to with stand pressure upto 5 bars.
- Smooth, fully rotatable tap.
- Stability tested pneumatically and hydrostatically.
- Tap turns every 360° without limitation.
- Flow shuts off every 90°.
- Minimal dead space in ports to ensure precise drug administration and maximum infusion flow. Continuous flow channels.
- Arrow indication marks on top to indicate direction of flow.
- Low profile for stable and safe positioning.
- Available in lipid resistant/non-lipid resistant varieties.
- Available with blue and red pegs for easier identification.
- Disposable, sterile and non-pyrogenic. Sealed blister packing.

### Technical Specifications

| Colour Code | Ref. No. | | Qty. in carton |
|---|---|---|---|
| | Non- Lipid Resistant | Lipid Resistant | Inner/ Outer |
| Blue | 4310012G | 4320012G | 50/500 |
| White | 4310022G | 4320022G | 50/500 |
| Red | 4310032G | 4320032G | 50/500 |

# Gloflexo™

## Extension tubing with 3 way Stop cock



**Three-way stopcock with an integrated extension tubing for minimizing manipulation during intravenous administration of fluids/drugs through an I.V. Catheter.**

- Minimizes chances of mechanical irritation and infection by taking.
- The administration site away from insertion site.
- The integrated three-way stopcock offers multiple infusion lines.
- Smooth internal surface to minimize turbulence.
- Disposable, sterile and non-pyrogenic.

### Technical Specifications

| Soft Blister Pack | | | |
|---|---|---|---|
| Length (cm.) | Int.- Ext. Dia. (mm.) | Ref. No. | Qty. in carton Inner/ Outer |
| 5 | 3.3-4.5 | 4270053G | 30/180 |
| 7 | 3.3-4.5 | 4270073G | 30/180 |
| 10 | 3.3-4.5 | 4270103G | 30/180 |
| 25 | 3.3-4.5 | 4270253G | 30/180 |
| 50 | 3.3-4.5 | 4270503G | 30/180 |
| 75 | 3.3-4.5 | 4270753G | 30/180 |
| 100 | 3.3-4.5 | 4271003G | 30/180 |
| 125 | 3.3-4.5 | 4271253G | 30/180 |
| 150 | 3.3-4.5 | 4271503G | 30/180 |
| 200 | 3.3-4.5 | 4272003G | 30/180 |
| 250 | 3.3-4.5 | 4272503G | 30/180 |

# GloManifold™

## Intravenous infusion system with multiple Stopcocks in line

**For infusing multiple drug therapies to the patient simultaneously.**

- Polycarbonate body and polyethylene lever.
- Easy to operate and smooth to turn.
- Large internal lumen.
- Highly resistant to pressure and chemicals over a wide range.
- Easily recognizable flow direction and flow path.
- 4 female luer locks and 1 male luer slip (incase of 3 port type).
- Limited rotation T handle with click function at each flowline.
- Recessed protector for manifold ports.
- ETO sterlised.

### Technical Specifications

| Type | Capacity | Ref. No. | Qty. in carton Inner/ Outer |
|---|---|---|---|
| 3 Port | 500PSI | 4910022G | 15/180 |

# Glopreg™

## I.V. Fluid Infusion Set with Flow Regulator

**Intravenous fluid infusion set with Flow Regulator to regulate the flow of IV fluid.**

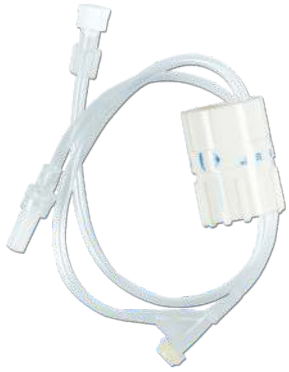
- Designed to control flow rates from 5 ml/hr – 300 ml/hr manually.
- Sharp, spike for easy insertion.
- Roller clamp for regulating fluid flow rate.
- Self sealing latex bulb for drug administration.
- Disposable, sterile and non-pyrogenic.

### Technical Specifications

| Product specification | Drops per ml. | Tubing Length (cm.) | Packing | Ref. No. | Qty. in carton Inner/ Outer |
|---|---|---|---|---|---|
| I.V. Insfusion set with airvent, Y-site, DEHP FREE tubing, Graduated flow regulator and small C-clamp | 20 | 150 | Ribbon Pouch<br>Paper Pouch | 441322G<br>441333G | 25/350 |

# Gloreg®

## I.V. Fluid Flow Regulator Extension Set



**I.V. Fluid Flow Regulator Extension Set to regulate the flow of IV fluid from an infusion set into an IV catheter.**

- Designed to control flow rate from 5ml/hr – 300 ml/hr manually.
- Built-in Y-connector injection site for extra medication.
- Two hand operation eliminates the danger of accidental tampering.
- Provision of male and female luer lock makes it compatible with other devices.
- Disposable, sterile and non-pyrogenic.

### Technical Specifications

| Product specification | Tubing Length (cm.) | Packing | Ref. No. | Qty. in carton Inner/ Outer |
|---|---|---|---|---|
| I.V. fluid extention set with Graduated flow regulator and Y-site | 45 | Soft Blister | 4660012G | 20/240 |

# Gloveins®

## Low Pressure Extension Tubing

**Extension Tubing for making administration of IV fluids more convenient.**

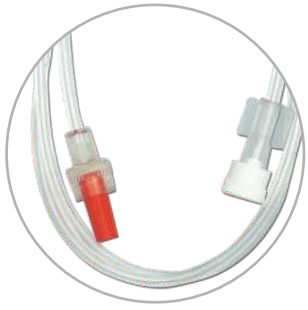
- Made from medical grade PVC.
- Minimizes the movement at the cannulation site by taking the fluid administration site away from the insertion site.
- Smooth internal surface to minimize turbulence.
- Disposable, sterile and non-pyrogenic.

### Technical Specifications

| Soft Blister Pack | | | |
|---|---|---|---|
| Length (cm.) | Int.- Ext. Dia. (mm.) | Ref. No. | Qty. in carton Inner/ Outer |
| 5 | 2.8-4.0 | 4260053G | 60/360 |
| 7 | 2.8-4.0 | 4260073G | 60/360 |
| 10 | 2.8-4.0 | 4260103G | 60/360 |
| 25 | 2.8-4.0 | 4260253G | 60/360 |
| 50 | 2.8-4.0 | 4260503G | 60/360 |
| 75 | 2.8-4.0 | 4260753G | 60/360 |
| 100 | 2.8-4.0 | 4261003G | 60/360 |
| 125 | 2.8-4.0 | 4261253G | 60/360 |
| 150 | 2.8-4.0 | 4261503G | 60/360 |
| 200 | 2.8-4.0 | 4262003G | 50/300 |
| 250 | 2.8-4.0 | 4262503G | 50/300 |

# Gloveins Alpha™

## High Pressure Extension Line



**High Pressure Extension Lines for arterial blood pressure monitoring.**

- Manufactured to withstand pressures upto 40 kg/cm2.
- Fitted with male and female luer locks for secure connection.
- Smooth internal surface to minimize turbulence.
- Disposable, sterile and non-pyrogenic.

### Technical Specifications

| Soft Blister Pack | | | |
|---|---|---|---|
| Int.- Ext. Dia. (mm.) | Length (cm.) | Ref. No. | Qty. in carton Inner/ Outer |
| 1.0-3.0 | 5 | 4290053G | 60/360 |
| 1.0-3.0 | 7 | 4290073G | 60/360 |
| 1.0-3.0 | 10 | 4290103G | 60/360 |
| 1.0-3.0 | 25 | 4290253G | 60/360 |
| 1.0-3.0 | 50 | 4290503G | 60/360 |
| 1.0-3.0 | 75 | 4290753G | 60/360 |
| 1.0-3.0 | 100 | 4291003G | 60/360 |
| 1.0-3.0 | 125 | 4291253G | 60/360 |
| 1.0-3.0 | 150 | 4291503G | 60/360 |
| 1.0-3.0 | 200 | 4292003G | 50/300 |
| 1.0-3.0 | 250 | 4292503G | 50/300 |

# Injection Stopper ™

## To block IV cannulas when not in use

**To block IV cannulas when not in use**

- Integrated one way valve within the stopper to allow drug administration into the cannula without unscrewing it.
- Available in latex/latex free varieties.

### Technical Specifications

| Type | Ref. No. | Qty. in carton Inner/ Outer |
|---|---|---|
| Latex | 4720012G | 250/2500 |
| Latex Free | 4720032G | 250/2500 |

# Luer Cap™

- Threaded stopper to block IV cannulas when not in use.
- Available in white colour.

### Technical Specifications

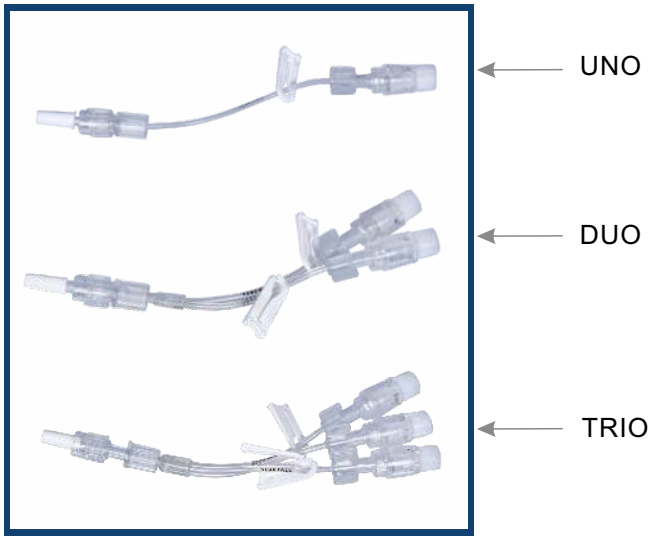
| Ref. No. | Qty. in carton Inner/ Outer |
|---|---|
| 4710012G | 250/2500 |

# Glolinn™

## Extension line with needle free valve

**FEATURES & BENEFITS:**

- Small bore multiple extension sets.
- Needless luer access ports provides virtually zero residual volume and high flow rates.
- Glolinn™ is light weight with an easy rotating luer lock which reduces the chances of pulling and kinking.
- Designed for multiple drug delivery.
- Valve features a straight-through, minimal dead space.
- Use of Glolinn™ reduces the chances for catheter/cannula related complications and improves the patient comfort.
- Low priming volume enable small-volume infusions.
- Silicone sealing membrane with slide clamp.
- Available in uno, duo, trio.
- DEHP free.
- Latex free.




**USAGE:**
Glolinn™ is designed to meet the needs of general I.V. therapy.

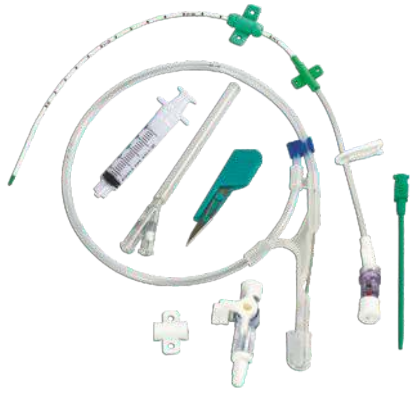
The ability of needle free connector is to prevent contamination of fluid path.

### Technical specifications

| Valve | Total length of Set | Approx. Priming volume (ml) | Ref. No. | Qty. Inner / Outer |
|---|---|---|---|---|
| UNO (1 way) | 15 cm | 0.25 ml | 4280101G | 50 / 500 |
| DUO (2 way) | 15 cm | 0.45 ml | 4280103G | 50 / 500 |
| TRIO (3 way) | 15 cm | 0.80 ml | 4280105G | 50 / 500 |

# Acent® 1

## Single Lumen Central Venous Catheter (Seldinger technique)



**Centrally inserted, single lumen central venous catheter.**

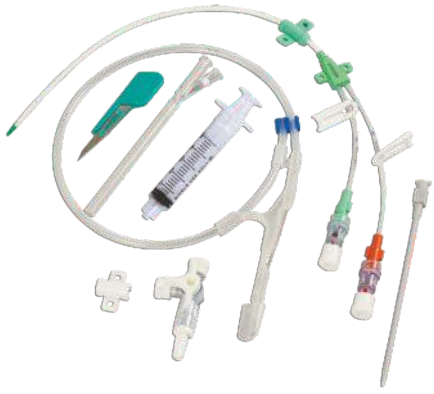
- For administration of hyperosmolar solutions, measuring CVP, haemodialysis, plasmapheresis, rapid infusion of fluid among other uses.
- Acent™ provides the benefit of polyurethane catheter which is soft, kink resistant, extremely biocompatible with excellent wear properties and elastic memory.

### Technical Specifications

| Lumen | | | | Catheter | | | |
|---|---|---|---|---|---|---|---|
| Size (Fr.) | Lumens | Lumen Gauge | O.D. (mm.) | Length (cm.) | Flow Rate (ml./min.) | Ref. No. | Qty. in carton Inner/ Outer |
| 6.0 | Single | 14 | 2.2 | 15 | 115 | 4766152G | 10/60 |
| 6.0 | Single | 14 | 2.2 | 20 | 105 | 4766202G | 10/60 |
| 6.0 | Single | 14 | 2.2 | 30 | 85 | 4766302G | 10/60 |
| 5.0 | Single | 16 | 1.7 | 15 | 50 | 4767152G | 10/60 |
| 5.0 | Single | 16 | 1.7 | 20 | 45 | 4767202G | 10/60 |
| 5.0 | Single | 16 | 1.7 | 30 | 40 | 4767302G | 10/60 |
| 4.0 | Single | 18 | 1.4 | 12 | 45 | 4768122G | 10/60 |
| 4.0 | Single | 18 | 1.4 | 15 | 40 | 4766152G | 10/60 |
| 4.0 | Single | 18 | 1.4 | 20 | 38 | 4768202G | 10/60 |

# Acent® 2

## Double Lumen Central Venous Catheter (Seldinger technique)



**Centrally inserted, double lumen central venous catheter.**

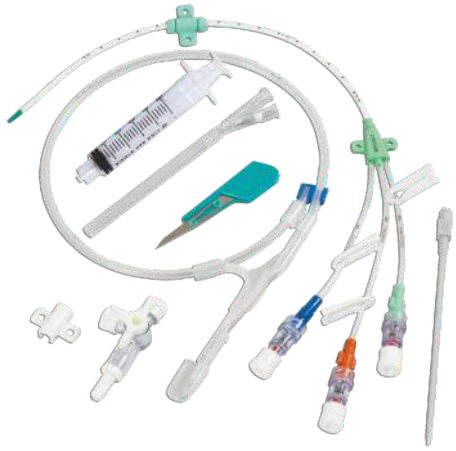
- For administration of hyperosmolar solutions, measuring CVP, haemodialysis, plasmapheresis, rapid infusion of fluid among other uses.
- Acent™ provides the benefit of polyurethane catheter which is soft, kink resistant, extremely biocompatible with excellent wear properties and elastic memory.
- Two separate non-communicating vascular access lumens within a single catheter body.
- Proximal lumen for blood sampling, medications and blood administration.
- Distal lumen for CVP monitoring, blood administration and medication.
- Reduces the necessity for multiple venipunctures.
- Exit ports of individual lumens are separated by appropriate distance in proportion to the catheter's French size.
- Coaxial catheter design maximizes inner diameter of central lumen for high flow capacity.
- Disposable, sterile and non-pyrogenic.
- Sealed blister packing.

### Technical Specifications

| Lumen | | | | Catheter | | | |
|---|---|---|---|---|---|---|---|
| Size (Fr.) | Lumens | Lumen Gauge | O.D. (mm.) | Length (cm.) | Flow Rate (ml./min.) | Ref. No. | Qty. in carton Inner/ Outer |
| 7.0 | Double | Proximal 16G; Distal 16G | 2.5 | 15 | 62 /62 | 4761152G | 10/60 |
| 7.0 | Double | Proximal 16G; Distal 16G | 2.5 | 20 | 62 /62 | 4761202G | 10/60 |
| 7.0 | Double | Proximal 16G; Distal 16G | 2.5 | 30 | 45/ 45 | 4761302G | 10/60 |
| 5.0 | Double | Proximal 20G; Distal 18G | 1.8 | 8 | 23/34 | 4762082G | 10/60 |
| 5.0 | Double | Proximal 20G; Distal 18G | 1.8 | 13 | 20/27 | 4762132G | 10/60 |
| 5.0 | Double | Proximal 20G; Distal 18G | 1.8 | 20 | 13/23 | 4762202G | 10/60 |

# Acent® 3

## Triple Lumen Central Venous Catheter (Seldinger Technique)



**Centrally inserted, Triple Lumen Central Venous Catheter**

- For administration of hyperosmolar solutions, measuring CVP, haemodialysis, plasmapheresis, rapid infusion of fluid among other uses.
- Acent™ provides the benefit of polyurethane catheter which is soft, kink resistant, extremely biocompatible with excellent wear properties and elastic memory.
- Three separate non-communicating vascular access lumens within a single catheter body.
- Proximal lumen for blood sampling, medications and blood administration.
- Distal lumen for CVP monitoring, blood administration, medications.
- Medial lumen exclusively for total parenteral nutrition.
- Reduces the necessity for multiple venipunctures.
- Exit ports of individual lumens are separated by appropriate distance in proportion to the catheter's French size.
- Coaxial catheter design maximizes inner diameter of central lumen for high flow capacity.
- Disposable, sterile and non-pyrogenic.
- Sealed blister packing.

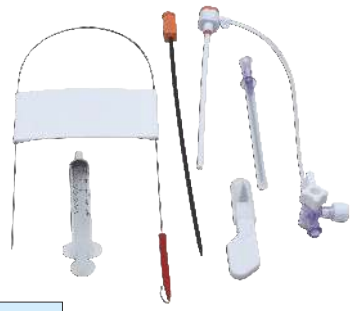
### Technical Specifications

| Lumen | | | | Catheter | | | |
|---|---|---|---|---|---|---|---|
| Size (Fr.) | Lumens | Lumen Gauge | O.D. (mm.) | Length (cm.) | Flow Rate (ml./min.) | Ref. No. | Qty. in carton Inner/ Outer |
| 7.0 | Triple | Distal 16G ; Proximal 18G ; Medial 18G | 2.5 | 15 | 62 / 27 / 27 | 4763152G | 10/60 |
| 7.0 | Triple | Distal 16G ; Proximal 18G ; Medial 18G | 2.5 | 20 | 51 / 25 / 24 | 4763202G | 10/60 |
| 7.0 | Triple | Distal 16G ; Proximal 18G ; Medial 18G | 2.5 | 30 | 40 / 19 / 18 | 4763302G | 10/60 |
| 7.0 | Triple | Distal 14G ; Proximal 18G ; Medial 18G | 2.4 | 15 | 60 / 30 / 30 | 4764152G | 10/60 |
| 7.0 | Triple | Distal 14G ; Proximal 18G ; Medial 18G | 2.4 | 20 | 52 / 24 / 24 | 4764202G | 10/60 |
| 7.0 | Triple | Distal 14G ; Proximal 18G ; Medial 18G | 2.4 | 30 | 41 / 21 / 21 | 4764302G | 10/60 |
| 5.0 | Triple | Distal 20G ; Proximal 22G ; Medial 22G | 1.8 | 8 | 29 / 17 / 17 | 4765082G | 10/60 |
| 5.0 | Triple | Distal 20G ; Proximal 22G ; Medial 22G | 1.8 | 13 | 25 / 15 / 15 | 4765132G | 10/60 |
| 5.0 | Triple | Distal 20G ; Proximal 22G ; Medial 22G | 1.8 | 20 | 20 / 10 / 10 | 4765202G | 10/60 |

Critical

# Introducer Set™

## Percutaneous Introducer Sheath Set



**Sheath Used For The Placement & Removal Of Vascular Catheter.**

- Medikit Introducer Set is used in wide ranging applications from interventional radiology to interventional cardiology.
- Primarily used to introduce balloon, electrode, diagnostic and other catheters into femoral vessels for diagnostic and therapeutic intervention in the coronary arteries.
- Each component has been scientifically designed and developed with utmost engineering precision keeping in mind the myriad requirements of clinicians
- Involved in interventional procedures.

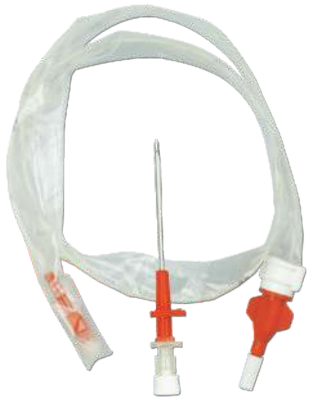
### Technical Specifications

| Sheath | | | | Dialator | | | Ref. No. | Qty. in carton Inner/ Outer |
|---|---|---|---|---|---|---|---|---|
| Size (Fr.) | I.D - O.D (mm.) | Effective Length (mm.) | Colour Code | I.D - O.D (mm.) | Effective Length (mm.) | Colour Coding | | |
| 5.0 | 1.90-2.40 | 110 | Light Grey | 1.15 / 1.80 | 150 | Light Grey | 4860052 | 5/50 |
| 6.0 | 2.30-2.80 | 110 | Green | 1.25 / 2.15 | 170 | Green | 4860062 | 5/50 |
| 7.0 | 2.65-3.15 | 110 | Orange | 1.30 / 2.45 | 170 | Orange | 4860072 | 5/50 |
| 8.0 | 2.95-3.45 | 110 | Grey | 1.60 / 2.80 | 170 | Grey | 4860082 | 5/50 |

| Introducer Cannula | | | Spring Guide Wire | |
|---|---|---|---|---|
| Gauge | O.D (mm.) | Effective Length (mm.) | O.D (mm.) | Length (cm.) |
| 18 G | 1.27 | 70 | 0.95 | 45 |

# Glocent®

## Single Lumen Polyurethane Central Venous Catheter (through Catheter technique)



**Peripherally inserted Single Lumen Central Venous Catheter.**

- For long term venous access, central venous pressure (CVP) monitoring, infusion of irritant medication, temporary pacing, hemodialysis/plasmapheresis etc.
- Specially coated, flexible polyurethane catheter.
- Removable stylet adds rigidity to the catheter during insertion.
- Extremely bio-compatible, soft and knik resistant catheter.
- Thromboresistant and fat resistant.
- Full length, four radio-opaque lines for accurate radiographic detection.
- Insertion depth marking every 5 cm to determine exact catheter position.
- Smooth tip aids atraumatic insertion.

### Technical Specifications

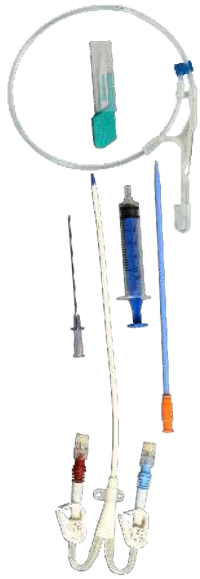
| Introducer cannula | | | | | PUR Catheter | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Size | I.D & O.D of teflon (mm) | Length of teflon (mm) | O.D of needle (mm) | Colour code | Size | I.D & O.D of catheter (mm) | Length of catheter (cm) | Priming volume (ml) | Flow rate of catheter (ml/min.) | Colour code | Ref. no. | Qty. in carton (inner/outer) |
| 12G | 2.2 X 2.6 | 45 | 2.1 | LIGHT BLUE | 14G | 1.25 X 1.95 | 32 | 0.65 | 75 | GREEN | 4752432G | 10/60 |
| | | 45 | | | | | 50 | 0.70 | 56 | | 4752452G | 10/60 |
| | | 75 | | | | | 50 | 0.70 | 56 | | 4752752G | 10/60 |
| | | 45 | | | | | 70 | 1.10 | 50 | | 4752472G | 10/60 |
| 14G | 2.0 X 2.3 | 47 | 1.83 | ORANGE | 16G | 1.1 X 1.73 | 32 | 0.45 | 53 | ORANGE | 4753432G | 10/60 |
| | | 47 | | | | | 50 | 0.60 | 45 | | 4753452G | 10/60 |
| | | 75 | | | | | 50 | 0.60 | 45 | | 4753752G | 10/60 |
| | | 47 | | | | | 70 | 0.80 | 30 | | 4753472G | 10/60 |
| 16G | 1.6 X 2.0 | 50 | 1.47 | GREY | 18G | 0.79 X 1.42 | 32 | 0.30 | 20 | YELLOW | 4754532G | 10/60 |
| | | 75 | | | | | 50 | 0.40 | 15 | | 4754752G | 10/60 |
| | | 50 | | | | | 70 | 0.50 | 12 | | 4754572G | 10/60 |
| 18G | 1.15 X 1.5 | 48 | 1.05 | GREEN | 20G | 0.60 X 1.0 | 32 | 0.20 | 6 | WHITE | 4756432G* | 10/60 |

*Without Stylet

# Haemodialysis Kit™

**FEATURES:**

- Haemodialysis catheter are single/double/multiple lumen catheter that provides temporary vasculer access for haemodialysis untill a permanent access is available or until another type of dialysis therapy is substituted.
- The multiple lumen catheter contains two large bore lumens that are connected to the dialysis machine to form a complete circuit for the removal and return of the patient's blood during treatment.



### Technical Specifications

| GAUGE CATHETER | SIZE | LENGTH OF CATHETER | O.D. OF CATHETER | FLOW RATE ml/min | Guide wire O.D/Length (mm/cm) | Dilator O.D/Length (mm) | Needle O.D/Length (mm) | REF. NO. | Qty. in Carton Inner/Outer |
|---|---|---|---|---|---|---|---|---|---|
| SINGLE LUMEN CATHETER | | | | | | | | | |
| 12G | 8FR | 13cm | 2.7 | 240 | 0.90/60 | 2.8/100 | 1.25/70 | 227A11B | 10/50 |
| 12G | 8FR | 16cm | 2.7 | 220 | 0.90/60 | 2.8/100 | 1.25/70 | 227A21B | |
| 12G | 8FR | 20cm | 2.7 | 200 | 0.90/60 | 2.8/100 | 1.25/70 | 227A31B | |
| DOUBLE LUMEN CATHETER | | | | | | | | | |
| 12G/12G | 11.5FR | 13cm | 4 | 300/300 | 0.95/60 | 4.0/150 | 1.25/70 | 228B42B | 10/50 |
| 12G/12G | 11.5FR | 16cm | 4 | 275/275 | 0.95/60 | 4.0/150 | 1.25/70 | 228B52B | |
| 12G/12G | 11.5FR | 20cm | 4 | 250/250 | 0.95/60 | 4.0/150 | 1.25/70 | 228B62B | |
| 12G/12G | 12FR | 13cm | 4 | 300/300 | 0.95/60 | 4.0/150 | 1.25/70 | 228C42B | |
| 12G/12G | 12FR | 16cm | 4 | 275/275 | 0.95/60 | 4.0/150 | 1.25/70 | 228C52B | |
| 12G/12G | 12FR | 20cm | 4 | 250/250 | 0.95/60 | 4.0/150 | 1.25/70 | 228C62B | |
| TRIPLE LUMEN CATHETER | | | | | | | | | |
| 12G/12G/16G | 12FR | 13cm | 4 | 285/85/81 | 0.95/60 | 4.0/150 | 1.25/70 | 229C72B | 10/50 |
| 12G/12G/16G | 12FR | 16cm | 4 | 180/68/64 | 0.95/60 | 4.0/150 | 1.25/70 | 229C82B | |
| 12G/12G/16G | 12FR | 20cm | 4 | 145/54/51 | 0.95/60 | 4.0/150 | 1.25/70 | 229C92B | |

Critical

# Gloeal®

## Endotracheal Tube (Plain)

**Tubular device designed to be inserted into the trachea through the oral/nasal cavity to secure the airway and maintain the gas exchange in the lungs.**

- Made from non-toxic, clear, transparent, thermoresistant medical grade PVC (Polyvinyl Chloride).
- Fitted with standard 15 mm connector for attachments to all standard ventilatory circuits in operation theaters or intensive care units.
- Graduated markings to display distance from the tip.
- Well marked to indicate the internal/external diameter.
- Nasoral tip suitable for both nasal and oral intubation.
- Full length radio-opaque lines to assess position of the tube radiographically.
- Murphy's eye near the tip to circumvent any obstruction.
- Disposable, sterile, non-pyrogenic.

### Technical Specifications

| E.T. Tube with Murphy Eye | | |
|---|---|---|
| I.D. (mm.) | Ref. No. Soft Blister | Qty. in carton Inner/ Outer |
| 2.0 | 6200205G | 25/200 |
| 2.5 | 6200255G | 25/200 |
| 3.0 | 6200305G | 25/200 |
| 3.5 | 6200355G | 25/200 |
| 4.0 | 6200405G | 25/200 |
| 4.5 | 6200455G | 25/200 |
| 5.0 | 6200505G | 25/200 |
| 5.5 | 6200555G | 25/200 |
| 6.0 | 6200605G | 25/200 |
| 6.5 | 6200655G | 25/200 |
| 7.0 | 6200705G | 25/200 |
| 7.5 | 6200755G | 25/200 |
| 8.0 | 6200805G | 25/200 |
| 8.5 | 6200855G | 25/200 |
| 9.0 | 6200905G | 25/200 |
| 9.5 | 6200955G | 25/200 |
| 10.0 | 6201005G | 25/200 |

# Gloeal Alpha®

## Endotracheal Tube (Cuffed)

**Tubular device designed to be inserted into the trachea through the mouth or nose to secure the airway and maintain the gas exchange in the lungs.**

- Made from non-toxic, clear, transparent, thermoresistant medical grade PVC (Polyvinyl Chloride).
- High volume, low pressure, evenly shaped cuff with a pilot balloon integrated to the tube for secure positioning inside the trachea .
- Fitted with standard 15 mm connector for attachments to all standard ventilatory circuits in operation theaters or intensive care units.
- Graduated markings to display distance from the tip.
- Well marked to indicate the internal/external diameter.
- Nasoral tip suitable for both nasal and oral intubation.
- Full length radio-opaque lines to assess position of tube radiographically.
- Murphy's eye at the tip to circumvent any obstruction.
- Disposable, sterile, non-pyrogenic.

### Technical Specifications

| E.T. Tube with Murphy Eye | | |
|---|---|---|
| I.D. (mm.) | Ref. No. Soft Blister | Qty. in carton Inner/ Outer |
| 2.5 | 6210255G | 25/200 |
| 3.0 | 6210305G | 25/200 |
| 3.5 | 6210355G | 25/200 |
| 4.0 | 6210405G | 25/200 |
| 4.5 | 6210455G | 25/200 |
| 5.0 | 6210505G | 25/200 |
| 5.5 | 6210555G | 25/200 |
| 6.0 | 6210605G | 25/200 |
| 6.5 | 6210655G | 25/200 |
| 7.0 | 6210705G | 25/200 |
| 7.5 | 6210755G | 25/200 |
| 8.0 | 6210805G | 25/200 |
| 8.5 | 6210855G | 25/200 |
| 9.0 | 6210905G | 25/200 |
| 9.5 | 6210955G | 25/200 |
| 10.0 | 6211005G | 25/200 |

Regional Anaesthesia

# Glosuc™

## Suction Catheter

- Suction Catheters are suitable for removal of secretion from mouth, trachea and bronchial tubes.
- Manufactured from non-toxic non-irritant medical grade PVC.
- Distal end is open with one lateral eye.
- Colour coded for instant size identification.
- Provided with universal funnel shape connector for safe connection to standard suction equipment.

### Technical Specifications

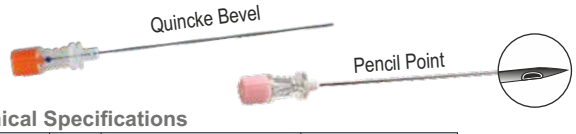
| Size (FG) | Colour of funnel | O.D. Catheter (mm.) | Ref. No. | Qty. in carton Inner/ Outer |
|---|---|---|---|---|
| 6 | Light Green | 2.00 | 5020065G | 50/450 |
| 8 | Blue | 2.67 | 5020085G | 50/450 |
| 10 | Black | 3.33 | 5020105G | 50/450 |
| 12 | White | 4.00 | 5020125G | 50/450 |
| 14 | Green | 4.67 | 5020145G | 50/450 |
| 16 | Orange | 5.33 | 5020165G | 50/450 |
| 18 | Red | 6.00 | 5020185G | 50/450 |
| 20 | Yellow | 6.67 | 5020205G | 50/450 |

# Glospine™

## Spinal Needle

**Intended for spinal (sub Arachnoid) anaesthesia.**

- Ultra fine quincke tip for better dura puncture appreciation and to prevent post dura puncture headache.
- Color-coded hub-stylet (International standard) for fast detection of the needle size.
- Optimal sized stylet prevents tissue coring and obstruction of the needle size.
- Transparent hub for fast detection of CSF.
- Needle length 3.5".
- Sterile for single use only.
- Made of superfine surgical steel.




### Technical Specifications

| Size | Colour Code | Quincke Bevel | Pencil Point | | | Ref. No. | |
|---|---|---|---|---|---|---|---|
| | | O.D of needle (mm) | O.D of needle (mm) | O.D of Introducer cannula (mm) | Introducer cannula Gauge x Length(mm) | Quincke Bevel | Pencil Point |
| 18G | Pink | 1.30 | N/A | N/A | N/A | 643018B | 643018BG |
| 19G | Ivory | 1.06 | N/A | N/A | N/A | 643019B | 643019BG |
| 20G | Yellow | 0.90 | N/A | N/A | N/A | 643020B | 643020BG |
| 21G | Green | 0.81 | N/A | N/A | N/A | 643021B | 643021BG |
| 22G | Black | 0.70 | 0.71 | 1.27 | 18Gx37 | 643022B | 643022BG |
| 23G | Blue | 0.66 | 0.66 | 1.08 | 19Gx37 | 643023B | 643023BG |
| 24G | Purple | 0.58 | 0.58 | 0.90 | 20Gx37 | 643024B | 643024BG |
| 25G | Orange | 0.55 | 0.50 | 0.90 | 20Gx37 | 643025B | 643025BG |
| 26G | Brown | 0.46 | 0.46 | 0.81 | 21Gx37 | 643026B | 643026BG |
| 27G | Grey | 0.41 | 0.40 | 0.70 | 22Gx37 | 643027B | 643027BG |

**- Effective length of needle : 90mm**
**- Qty. in carton Inner/Outer : 25/500**

# Epidural Mini Pack™

## Epidural Kit

**Kit contains Epidural Needle and Epidural Catheter of Corresponding size.**

- Specifically designed kink resistant yet structurally strong catheter with flexible tip making catheter placement convenient.
- Risk of inadvertent dura puncture or vessel rupture are markedly reduced with soft and flexible catheter tip.
- The uniquely designed coil reinforced body is the mainstay of its structural strength and makes the catheter non collapsible for long periods. Smooth exterior and ianner helix platform makes maneuverability easy and imparts radio opaque property to the catheter.
- Calibrated catheter depth marking make the placement exact and the colored catheter tip makes intact catheter depth marking make the placement exact and the colored catheter tip makes.
- Each 10 mm, beginning at 10 mm from the tip, up to 250 mm.
  2, 3, 4, 5 points, 2.5 mm each are located at 100, 150, 200, 250 mm from the tip respectively.
- Non-collasping holes near the tip makes drug dispersion uniform.
- Also contains specially designed filter disc with screwed connection for easy fit.

### Technical Specifications

| Needle | | | Catheter | | | Filter (µ) | Ref. No. | Qty. in carton Inner/ Outer |
|---|---|---|---|---|---|---|---|---|
| Gauge | OD (mm.) | Effective Length(mm.) | OD (mm.) | ID (mm.) | Effective Length(mm.) | | | |
| 16G | 1.70 | 80 | 1.00 | 0.60 | 1000 | 0.2 | 631016B | 20/ 240 |
| 18G | 1.30 | 80 | 0.85 | 0.45 | 1000 | 0.2 | 631018B | 20/ 240 |

Regional Anaesthesia

# Glociser™

## Respiratory Exerciser

**Helps to develop, improve and maintain respiratory fitness.**

- Useful in restoring and maintaining lung capacity of post operative ambulatory and COPD patients.
- Improves respiratory parameters, maximal exercise capacity and overall cardiopulmonary status.
- Air filter for enhanced protection.
- Transparent, well calibrated chambers for accurate estimation of exercise capacity.
- Soft, aesthetically coloured inspiratory tubing.
- Colour coded triple ball design for proper visual feedback.
- Sleek, stable design.

### Technical Specifications

| Product Specification | Ref. No. | Qty. in carton Inner/Outer |
|---|---|---|
| 3 ball model | 6040011G | 1/50 |

# Glomask®

## Oxygen face mask

**Transparent OXYGEN MASK meant to administer oxygen to patients.**

- Made from special non-toxic medical grade PVC.
- Two holes to allow carbon dioxide exhaled by the patient to escape.
- Nasal clip for secure fixation over the patient's nose.
- Elastic band for placement around the head.
- Transparent tubing to connect the mask to the oxygen source.

### Technical Specifications

| Product Specification | Type | Ref. No. | Qty. in carton Inner/ Outer |
|---|---|---|---|
| with tubing and nose clip | Adult | 6010021G | 20/200 |
| | Child | 6020021G | 20/200 |

# Gloneb™

## Nebuliser mask

**FACE MASK with an integrated NEBULIZER CHAMBER for nebulizing patients.**

- Transparent mask (with holes) made from non-toxic, medical grade PVC.
- Nebuliser chamber (6ml) to house the drug in liquid form with a funnel shaped vent to allow oxygen at high flows to convert the liquid drug into droplet form to reach the lungs.
- Soft, kink resistant, 200cms long non-collapsible extension tubing (STAR LUMEN) to be connected with the oxygen source.

### Technical Specifications

| Product Specification | Type | Ref. No. | Qty. in carton Inner/ Outer |
|---|---|---|---|
| with tubing, face mask and nose clip | Adult | 6060011G | 10/200 |
| with tubing and nose clip | Child | 6070011G | 10/200 |

# Glowin™

## Twin Bore Nasal Oxygen Set

- Suitable for easy and efficient administration of oxygen.
- Star lumen main tube to avoid accidental blockage.
- Soft and kink resistant PVC. Tubing.
- Soft twin prong nasal tips to ensure equal distribution of oxygen through both air passages which provides maximum patient comfort.
- Non-sterile
- Tube length: 210cm

### Technical Specifications

| TYPE | O.D OF TUBE (MM) | I.D OF TUBE (MM) | TUBE LENGTH (CM) | Ref.No. | Qty. in carton Inner/ Outer |
|---|---|---|---|---|---|
| ADULT | 4.90 | 2.80 | 210 | 6160011G | 25/400 |
| CHILD | 4.90 | 2.00 | 210 | 6170011G | 25/400 |

Respiratory Care

# Gloex™

## Mucus Extractor

**Used for aspiration of secretion from oropharynx in newly born babies to ensure free respiration.**

- Clear transparent container permits immediate visual examination of the aspirate.
- Also suitable for obtaining mucus specimen for microbiological examination.
- Spare plug cap is provided to seal the container for safe transportation of specimen to the laboratory or aseptic disposal of container.
- Low friction surface catheter is provided with open end silk smooth round tip, for trauma free insertion.
- Manufactured from transparent medical grade PVC. Sterile ready for use.

### Technical Specifications

| Size / gauge | Colour | capacity of Container | Ref. No. | Qty. in carton (Inner/Outer) |
|---|---|---|---|---|
| 8FG | Blue | 25ml | 5050085G | 25/350 |
| 10FG | Black | 25ml | 5050105G | 25/350 |
| 12FG | White | 25ml | 5050125G | 25/350 |
| 14FG | Green | 25ml | 5050145G | 25/350 |

# Glofant™

## Infant feeding tube

**Provide feedings and medications into the stomach.**

- Manufactured from soft, Non Toxic, medical grade PVC.
- Distal end is coned with two lateral eyes.
- Proximal end is provided with female luer mount for easy connection to feeding syringe.
- Tube with radio-opaque line.
- Smooth, low friction surface facilitates easy introduction.
- Disposable, Sterile, single use.

### Technical Specifications

| Size (Fr.) | Colour Code | O.D. (mm.) | Length (mm.) | Ref. No. Peel Open | Qty in carton Inner/ Outer |
|---|---|---|---|---|---|
| 5 | Grey | 1.7 | 510 | 5040055G | 100/1000 |
| 6 | Light Green | 2.0 | 510 | 5040065G | 100/1000 |
| 7 | Ivory | 2.3 | 510 | 5040075G | 100/1000 |
| 8 | Blue | 2.7 | 510 | 5040085G | 100/1000 |
| 10 | Black | 3.3 | 510 | 5040105G | 100/1000 |

# Gloryle®

## Ryel's Tube

- Made of Soft, frosted and kink resistant PVC tubing.
- Tube with radio-opaque line, marked at 50, 60 and 70 cms from the tip for accurate placement. Four lateral eyes for aspiration and administration.
- Manufactured from Non-toxic, Non-irritant medical grade PVC.
- Smooth, low friction surface facilitates easy introduction
- Disposable, Sterile, single use.

### Technical Specifications

| Size (Fr.) | Ext Dia. (mm.) | Length (cm.) | Colour Code | Ref. No. | Qty. in carton Inner/ Outer |
|---|---|---|---|---|---|
| 8 | 2.7 | 105 | Blue | 5080085G | 50/400 |
| 10 | 3.3 | 105 | Black | 5080105G | 50/400 |
| 12 | 4.0 | 105 | White | 5080125G | 50/400 |
| 14 | 4.7 | 105 | Green | 5080145G | 50/400 |
| 16 | 5.3 | 105 | Orange | 5080165G | 50/400 |
| 18 | 6.0 | 105 | Red | 5080185G | 50/400 |
| 20 | 6.7 | 105 | Yellow | 5080205G | 50/400 |

Gastroenterology

# Glocic™

## Thoracic catheter

- Suitable for effective drainage after Cardio-Thoracic & thoracic Surgery.
- Atraumatic & rounded open distal end with smooth eyes.
- With radio-opaque line and marking at every 2 cm from the last eye.
- Sizes: 16,20,24,28,32 & 36 FG
- Soft, frosted and kink resistant PVC Tubing -Matching size connector for easy connection to the drainage system.
- Proximal end is fitted with pull through tapered tongue.

### Technical Specifications

| Size (FG) | O.D of catheter (mm) | Without trocar | | With trocar | | Ref. No. | | Qty. on carton (Inner/Outer) |
|---|---|---|---|---|---|---|---|---|
| | | Effective length (mm) | No. of eyes | Effective length (mm) | No. of eyes | Without trocar | With trocar | |
| 8 | 2.7 | 450 | 4 | 160 | 2 | 62608A | C62608A | 25/150 |
| 10 | 3.3 | 450 | 4 | 180 | 2 | 62610A | C62610A | 25/150 |
| 12 | 4.0 | 450 | 4 | 180 | 2 | 62612A | C62612A | 25/150 |
| 14 | 4.7 | 450 | 4 | 200 | 2 | 62614A | C62614A | 25/150 |
| 16 | 5.3 | 450 | 4 | 200 | 2 | 62616A | C62616A | 25/150 |
| 18 | 6.0 | 450 | 4 | 200 | 2 | 62618A | C62618A | 25/150 |
| 20 | 6.7 | 450 | 4 | 350 | 2 | 62620A | C62620A | 25/150 |
| 22 | 7.3 | 450 | 4 | 350 | 2 | 62622A | C62622A | 25/150 |
| 24 | 8.0 | 450 | 6 | 350 | 2 | 62624A | C62624A | 25/150 |
| 26 | 8.7 | 450 | 6 | 350 | 2 | 62626A | C62626A | 25/150 |
| 28 | 9.3 | 450 | 6 | 350 | 2 | 62628A | C62628A | 25/150 |
| 30 | 10.0 | 450 | 6 | 350 | 2 | 62630A | C62630A | 25/150 |
| 32 | 10.7 | 450 | 6 | 350 | 2 | 62632A | C62632A | 25/150 |
| 34 | 11.3 | 450 | 6 | 350 | 2 | 62634A | C62634A | 25/150 |
| 36 | 12.0 | 450 | 6 | 350 | 2 | 62636A | C62636A | 25/150 |

***Also available***

**Glocic™**

**with TROCAR**

**THORACIC CATHETER**

# Medidrain®

## Wound Suction Drainage System

- Suitable to offer surgeons and doctors an effective device for close wound drainage under negative pressure post operatively with the option to use one or two catheters simultaneously.
- Graduated bellow container.
- Redon drain catheters are provided with radio opaque line and satin smooth eyes.
- Connecting tube is kink resistant and is provided with additional strength to withstand the suction.
- Easy to depress chamber to activate the suction of bellow unit by one person.
- Available with different catheter sizes with matching size curved needle to meet moderate to heavy drainage needs.

**Unit consists of**

- Bellow unit.
- Connecting tube with clamp and “Y” connector.
- Curved needle with matching catheter.
- Spare perforated catheter.

**Type Bellow Capacity**

- 800 ml.

**Supplied As:**

- Complete unit packed in a box.
- Sterile, ready for use.

### Technical Specifications

| Size (FG) | Colour code | O.D of perforated catheter (mm) | Length of perforated catheter (cm) | Capacity of Below container (ml) | Ref. No. |
|---|---|---|---|---|---|
| 10 | Black | 3.30 | 50 | 800 | 5090105 |
| 12 | White | 4.00 | 50 | 800 | 5090125 |
| 14 | Green | 4.70 | 50 | 800 | 5090145 |
| 16 | Orange | 5.30 | 50 | 800 | 5090165 |
| 18 | Red | 6.00 | 50 | 800 | 5090185 |

**- Qty. in carton (Inner/Outer): 1/30**

Surgery

# Gloyan™

## Yankauer Handle with Connecting Tube

**Suction of oral cavity and surgical field.**

- Rigid, angled, one-piece design, made from clear, medical grade PVC.
- Edges are smooth and clean. It has a bulbous tip and ribbed at proximal end to provide perfect grip.
- Clear tips permit visual monitoring of suction fluids.
- Connecting tubing with optimal draping qualities for maintaining a wall thickness to resist the most rugged environments.
- Used to clear copious and thick secretions and vomitus from oro-pharyngeal cavity and suction fluids and blood to provide clear surgical field.
- Disposable, Sterile, single use.



### Technical Specifications

| Product specifications | Tube length | Ref. No. | | Qty. in carton Inner/ Outer |
|---|---|---|---|---|
| | | Plain tip | Crown tip | |
| Suction tube with Crown & Plain tip | 8.2 ft. | 5310011G | 5310061G | 10/100 |
| | 9 ft. | 5310021G | 5310051G | 10/100 |
| | 10ft. | 5310031G | 5310071G | 10/100 |
| | 12ft. | 5310041G | 5310081G | 10/100 |

Surgery

# Glonel™

## Nelaton Catheter

**The single-use catheters are exclusively suitable for short term use.**

With its 40 cm length, the Nelaton Single-Use

Catheter is ideally suitable for males.

- **Atraumatic urine drainage** Sanitised, medical
- PVC and two rounded-off eyes positioned at the side ensure an optimal sliding quality and care for the sensitive tissue.
- **Fast size identification** The colour-coded funnel insert of the single-use catheter provides for a fast and certain identification of the sizes.
- Atraumatic eyes.
- Individually packed in sterile packaging.
- Transparent PVC providing full urine visibility.
- Contains no pyrogens and no latex.

### Technical Specifications

| Size (FG) | Colour Code | O.D of catheter (mm.) | Ref. No. | Qty. in carton Inner/ Outer |
|---|---|---|---|---|
| 6 | Light Green | 2.00 | 5010065G | 50/500 |
| 8 | Light Blue | 2.67 | 5010085G | 50/500 |
| 10 | Black | 3.33 | 5010105G | 50/500 |
| 12 | White | 4.00 | 5010125G | 50/500 |
| 14 | Green | 4.67 | 5010145G | 50/500 |
| 16 | Orange | 5.33 | 5010165G | 50/500 |
| 18 | Red | 6.00 | 5010185G | 50/500 |
| 20 | Yellow | 6.67 | 5010205G | 50/500 |

Urology

# GLOBAL MEDIKIT IN BRIEF

## GLOBAL MEDIKIT TEAM

The **Global Medikit** team offers operational experience, engineering solutions and materials research in the field of medical devices. The strong Global Medikit team of engineers, scientists, biochemists and operators work 24/7 to bring you the cutting edge medical device technology.

One of the hallmarks of the **Global Medikit** evolution as a major medical equipment manufacturer and exporter is the in-house development of proprietary equipment, manufacturing processes and techniques. This capability housed in our design and development centre, enables us to offer production answers to sometimes seemingly impossible challenges. **Global Medikit** is in other words, not only a resource for stringently controlled manufacturing, but also an innovation institute.

**Global Medikit** operates its manufacturing activities at Dehradun, Uttrakhand, India. Advantageous a pollution free industrial zone have been the key factors for concentrating the activities there. Each clean room has state of the art HVAC system HEPA filtration, positive pressure, controlled temperature and regulated relative humidity systems in place which provide a conducive environment for manufacturing.

### GLOBAL MEDIKIT R & D

Our research and engineering team functions in a number of capacities : design, development and refinement of products and processes. Our engineering staff can provide complete engineering services to support conceptual product assignments. The **Global Medikit** R & D team focuses on critical healthcare problems and finds effective product solutions.

### GLOBAL MEDIKIT PRODUCTION

State of art tools, robotics and statistical process controls are routinely used throughout the product development and manufacturing process. In its quest for quality, **Global Medikit** has successfully implemented a Quality Management System satisfying Quality System Standards ISO 9001 : 2008 ISO 13485 : 2003 and European Council Directive 93/42/EEC (ammended 2007/42/EEC concerning medical devices) as support to our quality assurance activity. We have achieved this certification through an independent audit by DET NORSKE VERITAS (DNV) ; Norway which is a reputed institute for certification.