

# CE DECLARATION OF CONFORMITY

According to annex III of the Council Directive 98/79/EEC on in vitro diagnostic medical device  
 We,

Alfa Scientific Designs, Inc.  
 13200 Gregg Street, Poway CA 92064, USA  
 Tel.: +1.858.513-3888 Fax: +1.858.513-8388

Declare under our sole responsibility that the following in vitro diagnostic medical devices, other than those covered by annex II and devices for performance evaluation

## PRODUCT LIST

IVD DEVICE NAME (Catalogue number)	FORMAT	EDMS CODE
<b>Cardiac Markers</b>		
<i>INSTANT VIEW</i> <sup>®</sup> CARDIAC 3-IN-1 WHOLE BLOOD/SERUM TEST (8503)	Cassette	12 70 13 90 00
<i>INSTANT VIEW</i> <sup>®</sup> TROPONIN I SERUM TEST (8572) (8577) <i>INSTANT VIEW</i> <sup>®</sup> TROPONIN I WHOLE BLOOD/SERUM TEST (8575)	Cassette & Dip-Strip Cassette	12 70 13 03 00
<b>Drug Test</b>		
<i>INSTANT VIEW</i> <sup>®</sup> AMPHETAMINE URINE TEST (3012) (3017)	Cassette & Dip-Strip	12 70 09 01 00
<i>INSTANT VIEW</i> <sup>®</sup> AMPHETAMINE (300) URINE TEST (3014) (3019)	Cassette & Dip-Strip	12 70 09 01 00
<i>INSTANT VIEW</i> <sup>®</sup> AMPHETAMINE (500) URINE TEST (3010) (3018)	Cassette & Dip-Strip	12 70 09 01 00
<i>INSTANT VIEW</i> <sup>®</sup> BARBITURATE URINE TEST (3152) (3157)	Cassette & Dip-Strip	12 70 09 03 00
<i>INSTANT VIEW</i> <sup>®</sup> BENZODIAZEPINE (BZD) URINE TEST (3132) (3137)	Cassette & Dip-Strip	12 70 09 04 00
<i>INSTANT VIEW</i> <sup>®</sup> BUPRENORPHINE/NORBUPRENORPHINE URINE TEST (2842) (2847)	Cassette & Dip-Strip	12 70 09 90 00
<i>INSTANT VIEW</i> <sup>®</sup> COCAINE (BENZOYLECGONINE) URINE TEST (3052) (3057)	Cassette & Dip-Strip	12 70 09 06 00
<i>INSTANT VIEW</i> <sup>®</sup> COCAINE (150) URINE TEST (3054) (3058)	Cassette & Dip-Strip	12 70 09 06 00
<i>INSTANT VIEW</i> <sup>®</sup> METHAMPHETAMINE (1000) URINE TEST (3032) (3037)	Cassette & Dip-Strip	12 70 09 01 00
<i>INSTANT VIEW</i> <sup>®</sup> METHAMPHETAMINE (500) URINE TEST (3033) (3038)	Cassette & Dip-Strip	12 70 09 01 00
<i>INSTANT VIEW</i> <sup>®</sup> METHAMPHETAMINE (300) URINE TEST (3030) (3035)	Cassette & Dip-Strip	12 70 09 01 00
<i>INSTANT VIEW</i> <sup>®</sup> MORPHINE (2000) URINE TEST (3092) (3097)	Cassette & Dip-Strip	12 70 09 08 00
<i>INSTANT VIEW</i> <sup>®</sup> MORPHINE (300) URINE TEST (3093) (3098)	Cassette & Dip-Strip	12 70 09 08 00
<i>INSTANT VIEW</i> <sup>®</sup> METHADONE URINE TEST (3172) (3177)	Cassette & Dip-Strip	12 70 09 07 00
<i>INSTANT VIEW</i> <sup>®</sup> OXYCODONE (100) URINE TEST (2862) (2867)	Cassette & Dip-Strip	12 70 09 08 00
<i>INSTANT VIEW</i> <sup>®</sup> OXYCODONE (300) URINE TEST (2863) (2866)	Cassette & Dip-Strip	12 70 09 08 00
<i>INSTANT VIEW</i> <sup>®</sup> PHENCYCLIDINE (PCP) URINE TEST (3112) (3117)	Cassette & Dip-Strip	12 70 09 09 00
<i>INSTANT VIEW</i> <sup>®</sup> PROPOXYPHENE (PPX) URINE TEST (2937) (2932)	Cassette & Dip-Strip	12 70 09 90 00
<i>INSTANT VIEW</i> <sup>®</sup> TCA URINE TEST (2972) (2977)	Cassette & Dip-Strip	12 70 09 10 00



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IN-VITRO DIAGNOSTICS ♦ CONTRACT R&D ♦ OEM ♦ FDA-REGULATED

IVD DEVICE NAME (Catalogue number)	FORMAT	EDMS CODE
INSTANT VIEW <sup>®</sup> TRAMADOL URINE TEST (4862) (4867)	Cassette & Dip-Strip	12 70 09 90 00
INSTANT VIEW <sup>®</sup> ALCOHOL URINE TEST (0008)	Dip-Strip	12 70 09 90 00
INSTANT VIEW <sup>®</sup> MARIJUANA/THC URINE TEST (3037) (3077)	Cassette & Dip-Strip	12 70 09 05 00
INSTANT VIEW <sup>®</sup> MDMA (ECSTASY, XTC) URINE TEST (2952) (2957)	Cassette & Dip-Strip	12 70 09 01 00
INSTANT VIEW <sup>®</sup> MULTI-DRUG SCREEN URINE TEST	Cassette & Dip-Strip	12 70 09 90 00
INSTANT VIEW <sup>®</sup> SPLITSCREEN MULTI-DRUG OF ABUSE URINE CUP TEST	CUP	12 70 09 90 00
VISION <sup>™</sup> DRUG URINE TEST CUP (5758)	CUP	12 70 09 90 00
ORAL VIEW <sup>®</sup> SALIVA MULTI-DOA TEST (4210)	Cassette	12 70 09 90 00
ORAL VIEW <sup>®</sup> SALIVA II MULTI-DOA TEST (4261) (4271) (4281)	Cassette	12 70 09 90 00
ORAL VIEW <sup>®</sup> SALIVA SINGLE DRUG OF ABUSE TEST (4748)	Cassette	12 70 09 90 00
<b>Fertility Test</b>		
INSTANT VIEW <sup>®</sup> PREGNANCY URINE TEST (2482) (2487)	Cassette & Dip-strip	12 70 05 02 00
INSTANT VIEW <sup>®</sup> PREGNANCY COMBO TEST (2483) (2488)	Cassette & Dip-Strip	
INSTANT VIEW <sup>®</sup> LILY PREGNANCY URINE TEST (2466)	Dip-strip	12 70 05 02 00
INSTANT VIEW <sup>®</sup> LADY PREGNANCY URINE TEST (2434)	Midstream	12 70 05 02 00
INSTANT VIEW <sup>®</sup> HCG REFERENCE-COMBO URINE TEST (2485)	Cassette	12 70 05 02 00
INSTANT VIEW <sup>®</sup> HCG COMBO II URINE TEST (2481)	Cassette	12 70 05 02 00
INSTANT VIEW <sup>®</sup> LH OVULATION PREDICTING TEST (2542) (2547)	Cassette & Dip-Strip	12 70 05 04 00
INSTANT VIEW <sup>®</sup> FSH URINE TEST (2562) (2567)	Cassette & Dip-Strip	12 05 01 04 00
<b>Other Test</b>		
INSTANT VIEW <sup>®</sup> H.PYLORI RAPID TEST – SERUM (9473) (9478)	Cassette & Dip-Strip	15 70 01 02 00
INSTANT VIEW <sup>®</sup> H.PYLORI RAPID TEST - WHOLE BLOOD/SERUM (9494)	Cassette	
INSTANT VIEW <sup>®</sup> STREP A RAPID TEST (9301)	Cassette	15 70 01 03 00

Meet the provisions of the Council Directive 98/79/EEC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured under Annex III section 4.
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to International Standards:

- EN ISO 13485:2003 – Quality Management System
- EN13612: 2002E, EN13640: 2002E, EN ISO 18113:2009, EN980: 2008E, and ISO14971:2007 E.



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*Signatory established within the EU who has been empowered to enter into commitments on our behalf:*

**European Authorized Representative (E.A.R.)**

**Obelis S.A.**

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**Representative :** Mr. Gideon Elkayam

**Position:** General Manager

**Signature:**

G. ELKAYAM  
C.E.O.

**Date:** 12/8/2011

**Obelis s.a. - O.E.A.R.C.**

Registered Address:  
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*Signatory on behalf of the manufacturer:*

**Manufacturer**

**Alfa Scientific Designs, Inc.**

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**Management Representative:**

Suni Dungan, QA/RA Director

**Signature:**

Suni Dungan

**Date:**

7/28/11