

CERTIFICATE OF CONFORMITY

Manufacturer:

LGM International, Inc.
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Product:**Product Numbers:****Cytology Processing Kit:**

1. Liqui-PREP™ Cytology Processing Kits - Product numbers: 30-300; 30-3001; 30-050; 30-1001; 30-050B; 30-100B1; 30-100B; 10 and 25 Test DEMO Kits (EV-10 and EV25).
2. Liqui-PREP™ Special Processing Kits – Product numbers: 40-300; 40-3001; 40-100;40-1001; 40-500; 40-050B; 40-0501;40-100B1; 40-100B; 80-2050, 80-3050; EV-8; FEV-8; 35-0300;35-0100; 35-0050; 35-0010.
3. Liqui-PREP™ Accessories – Product numbers: 60-010; 60-500;60-1000; 60-2000; 60-4000; 70-300; 70-3001; 70-500, 50-0020 and 80-1000.

The undersigned hereby declares on behalf of LGM International, Inc. of Melbourne, Florida, USA that the above-referenced products, to which this declaration relates, are in conformity with the provisions of **DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL; on in vitro diagnostics medical devices, and its ARTICLES AND ANNEXES.**

LGM International, Inc. Cytology Processing Kits have been designed and manufactured in accordance with the specifications detailed in Directive 98/79/EC, Annex I,III,X as a general IVD. These include but are not limited to:

Full Quality Assurance System; ISO13485; 2003; Notified Body Audits; Production Quality Assurance; Reagent Stability testing.

The manufacturing records required by Directive 98/79/EC are maintained at the corporate headquarters of LGM International Inc., 3030 Venture Lane, Suite 106, Melbourne, Florida 32934 USA.

LGM International, Inc. above referenced products have been cleared by the USA Food and Drug Administration (FDA) for sale within the USA and for world wide exportation.

Signed by :

NAME: David S. Gibbons
POSITION: Sr. Vice President, Dir. Of Quality
DATE: 6, February 2012
WEBSITE: www.lgmintl.com



ISO 13485: 2003
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