

**EC Declaration of Conformity**  
according to directive 98/79/EC, Annex II

**We,**

**EURO/DPC Limited**  
**Glyn Rhonwy**  
**Llanberis, Caernarfon**  
**Gwynedd LL55 4EL**  
**United Kingdom**  
**a subsidiary of Diagnostic Products Corporation**  
**5210 Pacific Concourse Drive**  
**Los Angeles, CA 90045-6900**  
**U.S.A.**

declare under sole responsibility that the following device to which this declaration relates, meets the essential health and safety requirements and is in conformity with the relevant sections of applicable EC standards and other normative documents. If changes are made to the product which is covered by this declaration of conformity, the declaration of conformity is no longer valid.

<b>Device type:</b>	<b>In Vitro Diagnostic Medical Device</b>
<b>Device name:</b>	<b>IMMULITE / IMMULITE 1000®</b> <b>Toxoplasma IgM (μ-Capture)</b>
<b>Catalog number:</b>	<b>LKTZ</b>
<b>EC Directives:</b>	<b>98/79/EC</b>
<b>National and other standards and technical specifications:</b>	<b>ISO 13485: 2003</b> <b>21CFR, Part 820 FDA cGMP</b>
<b>Notified body according to Annex IX:</b>	<b>Lloyd's Register Quality Assurance, 0088</b>

**Date/Signature of manufacturer or responsible party:**

**Title of signatory:**

  
Quality Assurance & Regulatory Affairs Manager 2005

9. Aug 05