

**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If changes are made to the product which is covered by this declaration of conformity, the declaration of conformity is no longer valid.

Device type: In Vitro Diagnostic Medical Device

Device name: IMMULITE 2000® / IMMULITE 2500®
Toxoplasma IgM (μ -Capture)

Catalog number: L2KTZ / L5KTZ

EC Directives: 98/79/EC

National and other standards and technical specifications: ISO 13485: 2003
21CFR, Part 820 FDA cGMP

Notified body according to Annex IX: Lloyd's Register Quality Assurance, 0088

Date/Signature of manufacturer or responsible party:

 9. Aug 05

Title of signatory: Quality Assurance & Regulatory Affairs Manager 2005