

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

**Manufacturer:**

**Siemens Healthcare Diagnostics Inc.**  
**5210 Pacific Concourse Drive**  
**Los Angeles, CA 90045-6900**  
**U.S.A.**

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changes are made to the product which is covered by this declaration of conformity, the declaration of conformity is no longer valid.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

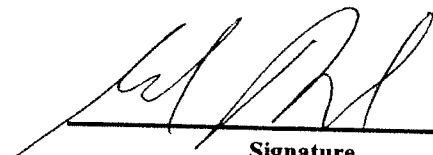
**Device name:** **IMMULITE® 2000 Chemiluminescent Substrate**

**Catalog number:** **L2SUBM**

**National and other standards and technical specifications:** **EN 375, EN 980, ISO 13485, EN 13612, EN 13640, EN 13641, ISO 14971, ISO/IEC 17050-1, 2, EN 17511, 21 CFR 820**

**EU Representative:** **Siemens Healthcare Diagnostics Limited**  
**Faraday House**  
**Sir William Siemens Square, Frimley**  
**Camberley, GU16 8QD**  
**United Kingdom**

**Signature/Date of  
Manufacturer or  
Responsible Party:**

  
\_\_\_\_\_  
**Signature**

*08/17/09*  
\_\_\_\_\_  
**Date**

**Name/Title of Signatory:**

*Kambiz Drake*  
\_\_\_\_\_  
**Print Name**

*Dir. of QA - Los Angeles*  
\_\_\_\_\_  
**Title**