

**EC Declaration of Conformity
according to directive 98/79/EC**

We,

**Siemens Healthcare Diagnostics Inc.
62 Flanders-Bartley Road
Flanders, NJ 07836
5210 Pacific Concourse Drive
Los Angeles, CA 90045**

declare under sole responsibility that the following equipment 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If changes are made to the product which is covered by this declaration of conformity, the declaration of conformity is no longer valid.

Equipment Type: In Vitro Diagnostic Medical Device

Model: IMMULITE® 2000 Xpi

Catalog Number: 030002-33

Serial Number: ALL

Harmonized Standards Used: EN 61326-1:2002, EN 61326-2-6:2006, EN 61010-1:2001, EN 61010-2-081:2002, EN 61010-2-101:2002

National and other standards and technical specifications: 21CFR, Part 820 FDA cGMP, ISO 13485: 2003, UL61010-1 2nd Ed., CAN/CSA-C22.2 No. 61010-1 2nd Ed.

Conformity Assessment Annex III

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

Date

Name/Title of Signatory: Ernest Joseph Sr. Manager, Regulatory Affairs
Print Name Title

5/14 2013