


**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If changes are made to the product which is covered by this declaration of conformity, the declaration of conformity is no longer valid.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	<u>Sept. 25th 2013</u> _____ Date
Name/Title of Signatory:	<u>Ernest Joseph</u> Print Name	<u>Sr. Manager, Regulatory Affairs</u> Title