

## EU Declaration of Conformity



We hereby declare that the product described below conforms to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc.  
62 Flanders-Bartley Road  
Flanders, NJ, 07836, USA

**Place of Manufacture:** CTP Mitcham  
47 Wates Way, Mitcham,  
Surrey. CR4 4HR, UK

**EC Authorized Representative:** Siemens Healthcare Diagnostics Manufacturing Ltd.  
Chapel Lane  
Swords, Co. Dublin, Ireland

**Product Name:** IMMULITE 2000 Systems Allergen Tube Caps

**Catalogue Number (REF):** L2ATC

**Siemens Material Number (SMN):** 10282837

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** DoC\_IMMULITE 2000\_AC

**Version:** 4.0

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.  
This declaration supersedes any declaration issued previously for the same product.*

**Signature:**

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**Sherrie Ryan**  
**Sr Manager Regulatory Affairs**  
**Siemens Healthcare Diagnostics Inc.**  
**Newark, DE 19714**

\_\_\_\_\_  
**Date**  
**[YYYY-MM-DD]**

EU DECLARATION OF CONFORMITY