SIEMENS

# EU Declaration of Conformity

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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.

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|---|---|
| **Legal Manufacturer:** | Siemens Healthcare Diagnostics Inc.<br>62 Flanders-Bartley Road<br>Flanders, NJ, 07836, USA |
| **Place of Manufacture:** | CARCLO TECHNICAL PLASTICS<br>Grant Road<br>Tucson, AZ 85705, USA<br><br>TN Michigan<br>1390 Industrial Park Dr.,<br>Sault Ste. Marie, MI 49783, USA |
| **EC Authorized Representative:** | Siemens Healthcare Diagnostics Manufacturing Ltd.<br>Chapel Lane<br>Swords, Co. Dublin, Ireland |
| **Product Name:** | IMMULITE 2000 Systems Reaction Tubes |
| **Catalogue Number (REF):** | LRXT |
| **Siemens Material Number (SMN):** | 10385206 |
| **Classification:** | General IVD |
| **Conformity Assessment Route:** | ANNEX III |
| **Document Identifier:** | DoC_IMMULITE 2000_RxnTubes |
| **Version:** | 5.0 |

*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:** Joseph Ernest

Digitally signed by Joseph Ernest
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**Ernest Joseph**
**Director Regulatory Affiars**
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**Date [YYYY-MM-DD]**

EU DECLARATION OF CONFORMITY