

EU Declaration of Conformity



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

EU DECLARATION OF CONFORMITY

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

Place of Manufacture: Caplugs
18704 South Ferris Place
Rancho Dominguez, CA 90220, USA

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

Product Names: See *List of Products*

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: DoC_IMMULITE_LMST_LSMC

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:

Ernest Joseph
Director Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY USA

Date
[YYYY-MM-DD]

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List of Products

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
IMMULITE 2000 Systems Microsampling Tubes	N/A	10385207 LMST
IMMULITE 2000 Systems Microsampling Tube Caps	N/A	10385205 LSMC

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