

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: GERRESHEIMER
Queretaro, S.A.
Av. Coahuila No. 9, Zona
Industrial Benito Juarez, Mexico

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

Product Name: IMMULITE 2000 Systems Diluent Tubes

Catalogue Number (REF): L2TZ

Siemens Material Number (SMN): 10385210

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: DoC_IMMULITE 2000_DTubes

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:

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

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY